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S. 746—THE REGULATORY IMPROVEMENT ACT OF 1999

HEARING

BEFORE THE

COMMITTEE ON GOVERNMENTAL AFFAIRS UNITED STATES SENATE

ONE HUNDRED SIXTH CONGRESS

FIRST SESSION

APRIL 21, 1999

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CONTENTS

WITNESSES

WEDNESDAY, APRIL 21, 1999

ALPHABETICAL LIST OF WITNESSES

Page

APPENDIX

S. 746, THE REGULATORY IMPROVEMENT ACT OF 1999

WEDNESDAY, APRIL 21, 1999

U.S. SENATE,
COMMITTEE ON GOVERNMENTAL AFFAIRS,
Washington, DC.

The Committee met, pursuant to notice, at 9:35 a.m., in room SD–342, Dirksen Senate Office Building, Hon. Fred Thompson, Chairman of the Committee, presiding.

Present: Senators Thompson, Voinovich, Lieberman, Levin, Durbin, and Edwards.

OPENING STATEMENT OF CHAIRMAN THOMPSON

Chairman THOMPSON. Good morning. Let us come to order, please. The Committee will consider the Regulatory Improvement Act of 1999, S. 746, which Senator Levin and I introduced in March with 15 of our colleagues.

We began our work on this legislation in the last Congress and S. 746 reflects changes that we made in negotiations with the White House. We are pleased that the administration has said the President would sign this proposal. We want to bring much needed improvement to the Federal regulatory system.

We believe that the American people deserve better results from the vast resources and the time that is spent on regulation. We support sensible regulations that help ensure a cleaner environment, safe food, safe workplaces, and reliable economic markets. Some continue to make increasingly isolated claims that the Regulatory Improvement Act would block or undermine important safeguards. We disagree with that. We want to make some common sense changes that will benefit all.

There is compelling evidence that our current rulemaking system is missing opportunities to deliver greater benefits at less cost. Ineffective and wasteful regulations erode the public's confidence in government and they undermine important programs that the public values. We have to regulate smarter.

This legislation will lead agencies to carefully consider and disclose the benefits and costs of different regulatory alternatives and seek out the smartest and most flexible solutions. It will help the Federal Government set smarter priorities to better focus money and other resources on the most serious problems. It will add transparency and accountability to the current regulatory process and help expedite important safeguards to reduce risk and save lives.

We have a fine lineup of witnesses from government, the private sector, public interest groups, and academia to provide input into the bill. I want to welcome them all and I look forward to hearing their views.

Before I call my first witness, I will recognize Senator Lieberman and other Members of the Committee who may be present for any opening comments. Senator Lieberman.

OPENING STATEMENT OF SENATOR LIEBERMAN

Senator LIEBERMAN. Thanks, Mr. Chairman. Let me say at the outset how much I appreciate the efforts that you and Senator Levin have made on this proposal over a long period of time. I recognize that this measure before us, S. 746, includes a number of changes made in response to some of the concerns expressed about the bill in the last session, and I thank you for that. Nevertheless, I may be one of those who remain skeptical about the approach of the legislation, for many of the reasons that I have expressed at the earlier hearings.

I continue to worry about unintended consequences and unforseen results. Trying to reform every type of regulation with a single law still seems to me to pose too high a risk to the public's health and safety. As democratically elected representatives, I know we all feel that we have an obligation to the people we serve to protect them from harm. That means, among other things, maintaining a strong defense, adequately staffing local police departments, but I think it is also equally our responsibility to protect people from breathing polluted air, drinking dirty water, eating contaminated food, working under hazardous conditions, and falling prey to consumer fraud.

There is a broad consensus in this country and in this Congress, I believe, that transcends party lines, for an appropriately active regulatory role for government. I think there is also a consensus that we ought to be enacting these protections in an equitable, efficient, and fact-based manner, in a manner that is open to as much public understanding and participation as possible.

In other words, we all support in the broad sense regulatory reform, but the question is how do we achieve it, and to me, the best way to achieve it is to target it statute by statute, not general and across the board.

An example of what I would call effective regulatory reform is the Safe Drinking Water Act Amendments that were enacted a few years ago, including a very targeted series of reforms that dealt with features unique to the problem of drinking water quality. Similarly, the Food Quality Protection Act, which focused on reforming the pesticide regulatory program, was narrowly tailored.

In both instances, negotiations led to agreements intended to increase future cost effectiveness while giving EPA the flexibility to address the higher priority risks to the public. Both bills passed the House and Senate by wide bipartisan margins.

Now, by comparison, let me offer an example of how I fear omnibus regulatory reform might affect regulation under individual statutes, and I am going to use the program regulating toxic air pollution under the Clean Air Act as an example. In 1990, when we amended the Clean Air Act, we recognized that toxic air pollu-

tion was not being adequately controlled. Literally thousands of pollution sources were releasing chemicals into the air that were known or suspected causes of cancer, birth defects, or other serious health problems. Many of these pollution sources were without controls, partly because it took too long for the agency to research and analyze the risks, as was required by the law.

Instead, Congress decided that there was already sufficient evidence of risk to justify regulating a list of particularly harmful chemicals, to narrow the field of regulation in that way, and we instructed EPA to set basic standards based on existing technologies without revisiting the questions of risk that Congress had already settled.

So if this bill, S. 746, applied to the air toxics program, I worry that EPA could be required to delay issuing standards for these toxic chemicals until the agency conducted extensive risk assessment for each standard, which was not the intention when we adopted the law. I know some of the witnesses today will discuss other examples of areas where S. 746 would affect regulation in ways that are probably not intended or may not be anticipated.

As troubled as I am about these examples, I am equally concerned about the ones that we are not going to hear about today and cannot foresee because this will have such a broad impact across all of our laws and regulations. I think it might be interesting to see a law-by-law survey showing how S. 746 would affect individual programs that now exist, whether at EPA or the Nuclear Regulatory Commission or the Food and Drug Administration, the National Highway Traffic Safety Administration, the Federal Aviation Administration, or any other agency.

We have already, in fact, enacted a number of regulatory reforms beyond those targeted statutes in recent years, and, as I have said before, I prefer to give those some more time and to have us evaluate how they are affecting environmental protection, consumer protection, and worker safety, for instance, until we go further.

These are the questions that leave me skeptical about the proposal, though I know it is well intended, and I look forward to the testimony today and to working with my colleagues on this Committee in pursuing the goal of fair and effective regulatory reform that I know we all share. I thank you.

Chairman THOMPSON. Thank you very much. Senator Voinovich.

OPENING STATEMENT OF SENATOR VOINOVICH

Senator VOINOVICH. Mr. Chairman, I am pleased that we are here today conducting this hearing on a very important issue of regulatory reform.

As you know, I testified before this Committee last year as a governor in support of the Regulatory Improvement Act. When I was Chairman of the National Governors' Association, I worked with the State and Local Government Coalition to make this bill one of our top priorities. That is an organization better known as the "Big 7." As a matter of fact, I spent over 40 hours in the last session trying to lobby this bill through this very Committee.

Fundamentally, what this legislation does is it says that we need to do risk assessment, cost-benefit analysis, objective standards that would be set for various agencies by OMB and the President's

Scientific Council. It would allow for peer review of that. It would look at alternatives to regulations that are being contemplated and it would finally provide an opportunity to file a lawsuit if an agency did something that was capricious and arbitrary—reasonable things that I think ought to be applied to all of our regulatory agencies.

One of the things that I was impressed with last year is how this Committee worked on a bipartisan basis to put this bill together and also with the White House to try and make it something that would be acceptable to the various groups that were concerned about this legislation. So this is an opportunity to take something that has really been debated and talked about and get it done this session. Again, I want to commend Senator Levin and our Chairman for the good job that they have done.

I also want to extend a warm welcome to a gentleman who was my mayor while I lived in the governor's residence in Columbus, Mayor Greg Lashutka. Mayor Lashutka was a leader in the unfunded mandates debate and is a strong proponent of the use of risk assessment and cost-benefit analysis.

Like Mayor Lashutka, I am a public servant who cares deeply about the needs of our environment and the health and well-being of our citizens. However, I am also concerned about the unnecessary and burdensome costs that are imposed on our citizens and State and local governments through Federal laws and regulations. As the lead governor on federalism for the National Governors' Association, I worked with the State and Local Government Coalition to help push the unfunded mandates relief legislation through and the Sage Drinking Water Act Amendments of 1996.

Much of the initial research showing regulatory cost on State and local governments was started in Ohio and Mayor Lashutka was one of the leading advocates of both pieces of legislation, as mayor and president of the National League of Cities.

These statutes set key precedents for the reforms that are envisioned in the Regulatory Improvement Act, as they made government more accountable based on awareness of risk, cost, and benefits. I would just like to remind the Members of the Committee, when we passed the amendments to the Safe Drinking Water Act, there were a lot of environmentalists and others that were opposed to it and we worked with those organizations and I will never forget being at the White House when the President signed that piece of legislation. It was that same kind of openness and working together that caused us to be successful with that and I am hopeful that same attitude will prevail with this legislation today.

I am not going to go into all the details about the costs that are involved in businesses and others complying with regulations, but I would like to say that, so often Congress fails to realize how much these regulations cost State and local government, our partners. As a former mayor and governor, I did not mind regulations, but I did mind regulations that when you looked at them and you looked at the costs involved and realized that the benefits that derived were not analyzed or looked at from a cost-benefit point of view, it was very frustrating.

So, Mr. Chairman, I am hopeful that we can get this legislation on the floor as soon as possible and that we can work with other

Members of this Committee that may have some reservations to see if we cannot answer their concerns and others that will be testifying before us. Thank you.

PREPARED STATEMENT OF SENATOR VOINOVICH

Mr. Chairman, I am pleased that you are conducting this hearing on this very important issue of regulatory reform. As you know, I testified before this Committee last year as a governor in support of the Regulatory Improvement Act. When I was Chairman of the National Governors' Association, I worked with the State and local government coalition to make this bill one of our top priorities. I am pleased to join you now as an original cosponsor of this important legislation.

I commend you and Senator Levin for your bipartisan work to enable Federal regulators to do a better job of protecting public health, safety and the environment.

I want to extend a warm welcome to a gentleman who was my mayor while I lived in the governor's residence in Columbus, Mayor Greg Lashutka. Mayor Lashutka was a leader in the unfunded mandates debate and is a strong proponent for the use of risk assessment and cost-benefit analysis.

Like Mayor Lashutka, I am a public servant who cares deeply about the needs of our environment and the health and well-being of our citizens. However, I am also concerned about the unnecessary and burdensome costs that are imposed on our citizens and State and local governments through Federal laws and regulations.

As the lead governor on Federalism for the National Governors' Association, I worked with the State and local government coalition to help push the Unfunded Mandates Reform Act (UMRA) and the Safe Drinking Water Act Amendments of 1996. Much of the initial research showing regulatory cost on State and local governments was started in Ohio. Mayor Lashutka was one of the leading advocates of both pieces of legislation as a mayor and president of the National League of Cities.

These statutes set key precedents for the reforms that are envisioned in the Regulatory Improvement Act, as they made government more accountable based on awareness of risk, cost, and benefits.

However, UMRA and the drinking water amendments have had limited applications. The Regulatory Improvement Act is needed to provide across-the-board cost-benefit analysis and risk assessment procedures at all Federal agencies, including independent agencies. I think it is time that we make Federal agencies—not just Congress—accountable for the decisions they make.

As a Nation, we spend vast sums of regulations. A report commissioned by the U.S. Small Business Administration estimates that regulations will cost the economy about $709 billion in 1999—more than $7,000 for the average American household.

Unfortunately, this burden on consumers and American businesses has not always resulted in maximum health or environmental protection. At times, it has diverted scarce resources that could be used for other priorities such as education, crime prevention and more effective protection of health and the environment.

The challenge facing public officials today is determining how best to protect the health of our citizens and our environment with limited resources. We need to do a much better job ensuring that regulations' costs bear a reasonable relationship with their benefits, and we need to do a better job of setting priorities and spending our resources wisely.

I think S. 746 will help achieve these goals by increasing the public's knowledge of how and why agencies make major rules. I also believe that this bill increases government accountability to the people it serves and will improve the quality of government decision-making by allowing the government to set priorities and focus on the worst risks first.

Mr. Chairman, I look forward to today's testimony.

Chairman THOMPSON. Thank you very much. Senator Levin.

OPENING STATEMENT OF SENATOR LEVIN

Senator LEVIN. Mr. Chairman, I want to thank you for calling the hearing, for your cosponsorship of this legislation, for sustaining the level of effort that is going to be necessary to see that this legislation becomes law. This task may be a Herculean one. I just hope it is not a Sisyphean one.

I came to the Senate because I believe that government can make a difference in people's lives, and I also know that government can waste money on a good cause, and when we do so, we jeopardize support for government acting to achieve the essential goals of public health, safety, and a clean environment. If we can do more with the resources that we have, or if we can spend less to achieve the protections that we want, we are wasting our money if we do not do that.

If we can choose between protecting 5,000 people for a cost of $100 million or 10,000 people for a cost of $110 million, I want to know about that choice. If it costs five times more to protect twice as many people, I want to know that, too. If we do not set up the systems so that we know what the choices and trade-offs are, then we are just being ostrich-like and putting our heads in the sand.

This bill is about information—information which we can use to judge the work that our government is doing to determine what the best methods are for achieving our goals. This bill directs agencies to consider all of our values, those that can be quantified and those that cannot be quantified. It directs agencies to learn about things, to get certain information. It does not tell the agencies when to regulate, what to regulate, or how to regulate. It just gives the information to agencies so that they can regulate wisely and it gives the public information that it can use to assess the agency's decision.

It is one thing to argue against a regulatory reform bill because of the concern that a bill that looks pretty good today may be modified in the legislative process to be unacceptable tomorrow, and I can understand that argument and I am very well aware of that concern. But it is another thing to argue that people should not know the costs and benefits of major Federal regulations. We should not be afraid of knowing what we are doing when we are regulating.

I have read the testimony of the opponents of the legislation and I must say that they are often describing a bill that I do not recognize and they are defending a cause which I do not support. The cause that I am referring to is not the cause of a cleaner environment or a safer workplace. Those are causes I do support, and strongly so. But the cause that they are too often defending and the cause that I do not support is choosing not to know the consequences of our actions as a government.

This bill has broad bipartisan support, including the support of the Democratic leader, Senator Daschle. It also, obviously, has opposition. The President has agreed to sign this bill if it comes to him in its current form, and I would ask, Mr. Chairman, if it already has not been done, that a statement of Jack Lew, the Director of the Office of Management and Budget, that says that if S. 746 emerges from the Senate and House as you now propose, the President would sign it, be inserted in the record.[1]

Chairman THOMPSON. Without objection.

Also, Mr. Chairman, I would ask, if it has not already been inserted in the record, that the statement of the General Accounting

[1] The prepared statement of Jacob J. Lew, Director, Office of Management and Budget, appears in the Appendix on page 59.

Office on this bill be inserted in the record, and I would just simply read one paragraph on page 8.[1]

"S. 746 contains a number of provisions designed to improve regulatory management. These provisions strive to make the regulatory process more intelligible and accessible to the public, more effective, and better managed." The GAO concludes that paragraph by saying, "Passage of S. 746 would provide a statutory foundation for such principles as openness, accountability, and sound science in rulemaking."

Chairman THOMPSON. It will be made part of the record, without objection.

Senator LEVIN. Finally, Mr. Chairman, we all want an effective government that protects public health, welfare, and the environment. We all want our government to achieve those goals in the most sensible and efficient way possible. We all want to do the best that we can with what we have and to do more good at less cost, if possible. That is the intention of this bill and I believe that this bill will help us achieve that.

Thank you, and I also want to thank Senator Voinovich, who, when he was a governor testified here was so effectively on this legislation last year.

Chairman THOMPSON. Thank you very much. Senator Durbin.

OPENING STATEMENT OF SENATOR DURBIN

Senator DURBIN. Thanks very much, Mr. Chairman. I suspect I am a minority on this panel, but I have serious problems with this legislation, as I did when we last considered it. I agree that we need regulatory reform. We need to make every effort to reduce bureaucracy and red tape and litigation. But I do not agree that a child's health can be measured in dollars or that public safety should take a back seat to a marathon of bureaucratic haggling. I am fearful that this bill would slow down the regulatory process by imposing new responsibilities on Federal agencies for net cost-benefit determination, risk assessment, and peer review.

If you take a look at the track record of this Federal Government in responding to national crises, it really suggests that we are not quick to respond in the time when most Americans think we would. In 1993, the E. Coli outbreak really signaled that our food safety inspection process needed to be looked at and brought up to date. Well, it took us over 3 years to get started and to implement the HACCP process, and, frankly, it will not be operational until the year 2000. So this is a process that is already slow and will be made even slower if this legislation passes.

Look at the OSHA situation. OSHA is an agency which is supposed to protect the health and safety of workers. It takes 10 years, on average, to issue a worker health and safety protective standard. This bill will make it longer. It took the EPA 10 years to issue a clean water rule. This bill will make it longer.

When you look at all these, you have to stop and ask whether or not we are prepared to put the people in place at these agencies to implement this bill, and the honest answer is we are not. In this

[1] The prepared statement of the General Accounting Office on S. 746 appears in the Appendix on page 71.

same building, a budget resolution is talking about cuts of up to 12 percent in terms of the budgets of some of these agencies. This bill will impose new standards, new responsibilities on these agencies without even a hint that we are going to provide the personnel so that they can keep up with these new requirements.

The people on the other side, in the private sector, will be making their investment in their attorneys and researchers and scientists. We will not make the investment on the government side to protect public health. We will impose new responsibilities and mandates on these agencies before they can issue regulations for health and safety, and yet we will not provide them the people to implement those mandates. So there will be fewer people involved in inspection, and fewer people involved in implementation.

The net result, of course, the American consumers and families are the losers. We might have a good idea about how to protect them, but we have to clear all the new hurdles in this bill and we do not have the people to do it. That, I am afraid, is the bottom line.

As it is currently written, this bill will result in more bureaucracy, more red tape, and more delay. Congress does not and should not have to choose between business and consumers. There has to be a sensible approach that can protect both interests.

Thank you, Mr. Chairman.

Chairman THOMPSON. Thank you very much.

I would like to recognize our first panel. We are pleased to have today with us, as Senator Voinovich indicated, the Hon. Gregory Lashutka, Mayor of the City of Columbus, Ohio.

We also have Robbie Roberts, the Executive Director of the Environmental Council of States, and Scott Holman, the Chairman of the Regulatory Affairs Committee of the U.S. Chamber of Commerce.

Thank you for being with us here today. Mayor, do you have a comment that you would like to make?

TESTIMONY OF HON. GREGORY S. LASHUTKA,[1] MAYOR, CITY OF COLUMBUS, OHIO

Mr. LASHUTKA. I do, Mr. Chairman. Thank you very much to the Members of this Committee and particularly warm greetings to my Senator, Senator Voinovich. I do appreciate the opportunity to provide testimony today on the Regulatory Improvement Act, S. 746.

I do want to echo the comments of others commending you, Mr. Chairman, and Senator Levin, particularly, on your expertise and commitment in making the regulatory process, in fact, more accountable to the people of this country.

As you may be aware, our city has looked at this issue for a number of years and we have been stressing the need for Federal procedures to reduce the very unintended consequences that Senator Lieberman had alluded to. Those unintended consequences are a result of mandates and regulations on significant occasions that affect our Nation's cities and towns.

Not only have I weighed in on behalf of our citizens on regulatory reform, but today I am appearing and testifying on behalf

[1] The prepared statement of Mr. Lashutka appears in the Appendix on page 80.

of the National League of Cities. The National League of Cities is the largest and the oldest organization representing cities from the East and West Coast and North and South, citizens that live in each of your States, from the largest to smallest. We are proud of our two past presidents—who are now in the Senate—including Senator George Voinovich and Senator Dick Lugar from Indiana.

Our organization represents 135,000 cities and towns across the country. Significantly, over 75 percent of those are from the smallest cities, with populations less than 50,000, cities reflected in your State, Mr. Chairman, Tennessee, and all the States represented by this Senate.

We strongly, as an organization—the National League of Cities—support the Regulatory Improvement Act of 1999. We are not alone. All the lead organizations representing the Nation's local governments, known as the "Big 7," are in support of passing this legislative and regulatory goal that will benefit the States and local government and most particularly their constituents. I am pleased that a letter should be forthcoming to you later today,[1] Mr. Chairman, from all those State and local government associations, known as the "Big 7," supporting this legislation. Passage of this bill is part of the federalism partnership agenda of the "Big 7."

The "Big 7" is also pleased to work with you and Senator Levin and Members of this Committee for the passage of the Regulatory Right-To-Know Act, S. 59, as well as the preemption bill that we are currently drafting. The "Big 7" believes these bills are a significant legislative package in their entirety to clarify the intent of Federal regulation and legislation. While this will allow further input from those of us who really have the main responsibility in implementing that, State and local government, we applaud your distinctive leadership on this issue.

While the Unfunded Mandates Relief Act of 1995 had a very positive impact on the shift of burden of cost on State and local government, it only addressed the legislative process. It does not address Federal regulations. S. 746 will enclose the gap that is left open that allows costly regulation on cities by providing for better consultation with State and local government for risk assessment and cost-benefit analysis of the legislation that would be proposed.

It is imperative that all levels of government work together to deliver the most efficient services to constituents that are both of ours, Federal, State, and local. Our constituents expect no less than the Federal, State, and local government to work together, providing effective service. And the most effective way for us to deliver those services is for each level of government to stay within its most effective and efficient roles.

These lines are becoming more and more obscure as the Federal Government continues to regulate various sectors in our local communities, too often without consideration of the very impact that is a concern by both sides on this issue. Gaining an equal voice through this legislation in the regulatory process will allow cities and towns to demonstrate the impacts before it is too late. We

[1] The letter from the "Big 7," dated April 21, 1999, to Senator Thompson appears in the Appendix on page 238.

must balance health, safety, and economic needs and wants of our citizens.

Here is the core problem in my opinion. Each Washington bureaucracy, or sometimes even a Congressional committee, views each of our cities through a soda straw on the given issue at hand for that day. It is only one look at one point in time on one issue.

For example, we promote regulations on underground storage tanks, and that is one set of legitimate issues, and yet we may or may not correlate, and quite often does not, with our stormwater runoff or how we are pursuing the issue on drinking water that was raised earlier or other environmental issues that are of equal concern to our citizens. But we are forced on a local level to triage the most important. The Federal Government wants us to address all of those, quite often at the same time.

We are a microcosm that interacts, a living, breathing, dynamic region and not just a government, but we have to deal with businesses, large and small, not-for-profit organizations, and neighborhoods, all who have some dynamic with us. We look to our businesses, the economic energy and revenues, to provide basic services, and all the mandates have an impact, good or bad, upon us. Sometimes they, in fact, do have a rational scientific basis. At other times, they do not.

The problem, again, as I mention, is tunnel vision. Each regulation may take a few pages in the *Federal Register,* but I would suggest to you as we were successful in passing the Unfunded Mandates Relief Act that the pile of regulations our city had affected is taller than you, Senator, taller than the rest of the Senators on your Committee, and taller than myself on an annual basis and we are responsible for reviewing those, as are others.

This past year, our cities and towns have seen regulations that preempt our cities and towns in decision making on authority on local issues and regulations and those cost us millions of dollars. An example, our Occupational Health and Safety Administration mandated cities who were in OSHA State plans would have to do the following manning standards to respond to interior structural fires, a legitimate cause, but our cities and towns support those efforts and regulations and the need for greater health, safety, and environment. But this regulation was implemented at a period when fire is at a historical low.

I have other testimony, but I notice the red light is on and I would be more than happy to tender that to the written testimony if you like, Mr. Chairman.

Chairman THOMPSON. All written statements will be made a part of the record. Thank you very much.

Mr. Roberts.

TESTIMONY OF ROBERT E. ROBERTS,[1] EXECUTIVE DIRECTOR, ENVIRONMENTAL COUNCIL OF STATES

Mr. ROBERTS. Mr. Chairman, Members of the Committee, thank you for the opportunity to appear before you this morning regarding the Regulatory Improvement Act of 1999.

[1] The prepared statement of Mr. Roberts appears in the Appendix on page 88.

My name is Robbie Roberts. I am the Executive Director of the Environmental Council of States. The Environmental Council of States is the national nonpartisan, nonprofit association of State and territorial environmental commissioners. Each State and territory has some agency, called different things in different States and located in different places in different State Governments, that corresponds to the U.S. Environmental Protection Agency. Our members are the States and territories and the people with whom we work are the officials who manage the environmental agencies in the States and territories. Currently, 52 of the 55 States and territories are members of the Environmental Council of States.

We are delighted to join with our friends and colleagues in the National Governors' Association, the Council of State Governments, the National Conference of State Legislatures, the National Association of Counties, the U.S. Conference of Mayors, and the National League of Cities to support this legislation.

Robert W. Varney is the Commissioner of the New Hampshire Department of Environmental Services. He is our current President. He signed the letter which has been provided to the Committee already. He regrets he could not be with you today but asks that I formally present that letter, which I have done.[1]

Let me read one paragraph from Commissioner Varney's letter that I think captures the central issues in this legislation. "We support consideration of cost-benefit analysis because to do otherwise is to risk misapplication of limited resources. We support risk analysis because to do otherwise may be to attack the wrong problems. Expanding the participation of State and local government officials in the development of national environmental requirements can only strengthen the final products."

Mr. Chairman, the extent to which environmental protection is performed not by the Federal Government but by the States and local governments is not perhaps generally understood. Let me give you four measures of the degree to which environmental responsibilities have been shifted to the States.

First, approximately 75 percent of State environmental and natural resources spending is State funds, not Federal funds.

Second, approximately 78 percent of enforcement actions are taken by State environmental officials, not by Federal environmental officials.

Third, about 96 percent of the total environmental quality information currently held in Federal databases was gathered by State environmental officials, not by Federal environmental officials.

And fourth, of all the major environmental programs that were designed to be delegated to the States, about 71 percent have been delegated and are currently being administered by the States.

This is a success story. We have talked over the last few years about devolution of responsibility to the States and much of that devolution has taken place. As States have increased their capacity and as environmental protection has become increasingly important to the general public, more and more responsibilities have been moved to the level of government best able to carry them

[1] The letter from Mr. Varney to Senator Thompson dated April 16, 1999, appears in the Appendix on page 240.

out—State and local governments—which are best able because they are closest to the problem, closest to the people who must solve the problems, and closest to the communities that must live with the solutions.

In this situation, it becomes increasingly important that taxpayer resources be directed to the most important problems. Problems sometimes seem to be infinite. Resources are finite. To help prioritize problems and define where to apply limited resources, new and innovative techniques are required. Risk analysis and benefit cost analysis of proposed Federal rules and regulations can improve our ability to spend taxpayers' money wisely.

Finally, we support actions which make the Federal rulemaking process easier to understand and easier to participate in. By making more information available, all interested participants, including State and local government officials, can help assure that rules and regulations better meet the needs of the local area and of the Nation.

Thank you, Mr. Chairman, for the opportunity to make this presentation.

Chairman THOMPSON. Thank you very much. Mr. Holman.

Senator LEVIN. Could I just give a special welcome to Mr. Holman, who comes from my home State of Michigan, an area of the State where my great grandparents happened to come from, but more important, he has been active in the small business community, the education community, and I just want to give him a special welcome.

TESTIMONY OF SCOTT L. HOLMAN,[1] CHAIRMAN, REGULATORY AFFAIRS COMMITTEE, U.S. CHAMBER OF COMMERCE

Mr. HOLMAN. Thank you, Senator. Chairman Thompson, Ranking Member Lieberman, and Members of the Committee on Governmental Affairs, I am Scott Holman, owner and President of Bay Cast, Incorporated, of Bay City, Michigan. My company is a small manufacturer of large custom steel castings for the automotive tooling, machine tool, steel mill, and construction industries.

I am a member of the U.S. Chamber of Commerce's Board of Directors, Small Business Council, and Chairman of the Chamber's Regulatory Affairs Committee. I was a delegate to the 1995 White House Conference on Small Business and served on the Michigan Chair for both Regulatory and Taxation Committees.

I would like to thank you for the opportunity to testify on behalf of the Chamber, of which more than 96 percent of the members are small businesses, 71 percent of which have 10 or fewer employees. Therefore, we are particularly cognizant of the problems of smaller businesses.

Mr. Chairman, first, I would like to salute you and my Senator, Mr. Levin, for your leadership in making the Federal regulatory process more accountable and responsive to the regulated community, which includes all Americans. The growing spirit of bipartisanship in Congress for improving the regulatory system is very encouraging to me, along with the Regulatory Improvement Act, the Mandates Information Act, the Regulatory Right-To-Know Act,

[1] The prepared statement of Mr. Holman appears in the Appendix on page 91.

and the Small Business Paperwork Reduction Act, all examples of both parties coming together to provide some common sense rationality to the fragmented and overly complex regulatory system with which small businesses must deal.

Government paperwork, red tape, and regulations are among the greatest concerns facing small business owners today. The regulatory burdens imposed upon business in the United States are astounding. Recent studies estimate that the compliance costs of Federal regulations are more than $700 billion annually and small businesses bear much of this cost.

A 1995 study conducted by renowned economist Tom Hopkins found that businesses with fewer than 20 employees have almost twice the regulatory cost per employee than operations with 500 or more employees. I, like other small businesses across our Nation, find it frustrating that regulators cannot seem to figure out that regulations and paperwork cost not only money but time spent in figuring out how to comply.

For example, regulation relevant to just one of the many raw materials used in the metal casting industry deals with sand. Every year, foundries use more than 100 million tons of this material. Approximately 90 to 95 percent of the foundry sand used is not toxic when tested by the EPA required method. Five to 10 percent portion of that sand fails to pass a toxicity test. It is easily identifiable by a specific production process at the source. So the hazardous portion could easily be disposed of differently than the non-hazardous portion.

Unfortunately, the regulation does not allow us the flexibility to do the sensible thing. In fact, an independent study conducted in Wisconsin shows the used foundry sand to be less of a threat to the human health than even natural background soils. This material is a commodity that can be made available for reuse in numerous construction related applications. Technology also exists to convert foundry sand into glass or for roofing or for other materials.

Yet foundries across the Nation face tremendous hurdles in getting approval for beneficial reuse of this byproduct from their processes. So foundries end up paying an ever-increasing disposal cost for sand. The burdens imposed by these restrictions amount to significant costs for small facilities, like mine. Disposal costs for these and other reusable materials is approximately $500 million for the industry, depending on the landfill tonnage and fees at the time. This is too much to pay for materials that have been judged to be cleaner than dirt.

It is sad and ironic that our society and small metal casters are forced to pay a double cost because of excessive regulation. We lose the opportunity to convert sand into useful economic items and we must instead pay the high cost of needless disposal. So the sand fills up valuable landfill space while it could have been recycled to make new products. Is this environmentally friendly regulation?

So information is the power. This has never been as true as it is in today's information age. The Regulatory Improvement Act is about ensuring a healthy exchange of information on government decisions between people and their government. One of the founding principles of our Nation was the ability of people to question

their government. The Regulatory Improvement Act of 1999 provides power of the American people through greater information.

While not an expert theorist on risk analysis, I am a practicing expert on cost-benefit analysis and risk assessment, as are most surviving entrepreneurs. If I fail to set priorities based upon well-grounded information, I risk not being able to make my payroll. If I fail to make appropriate risk assessment, I can lose the order that may keep my people working, or worse, maybe get the order and place the whole operation at risk for our very survival. If I fail to use well-founded plausible assumptions in the allocation of my limited resources and commit capital in the wrong areas, I can get into trouble. So I need that kind of information.

The burdens for small business go far beyond the direct cost of compliance. Most of us cannot afford to have the full or even part-time environmental staff in-house and therefore face escalating costs of consultants and attorneys just to comprehend our obligations under the hailstorm of regulations. Are we going to tailor our laws to the actual risks out there? Which regulations are justified, those that make an appreciable difference in our health and quality of life or those that force us to jump through new hoops and pile up paper and consume capital and human resources with questionable results?

S. 746 is a pragmatic and measured attempt to correct real flaws in our system without giving up the protection that the public wants. I, for one, do not want to poison my workers or my neighbors or destroy the beauty of the community, but I have no interest in paralyzing our regulatory system with hurdles and delays.

This legislation forces a degree of feet-on-the-ground accountability through risk analysis, cost-benefit analysis, open communication, contextual comparison, and peer review. Ultimately, reasonable people of good will can disagree on the details, but the overarching and powerful concept of this legislation must be given a try.

The Committee deserves to be commended for its efforts to provide greater accountability and better decision making into the regulatory process and the Chamber appreciates the difficulty involved in pursuing the reform. We encourage the Committee to continue working toward reform this year so that these crucial reforms can become law.

Again, thank you for this opportunity to testify at this time. I am willing to answer any questions that you have, and Mr. Chairman, I request that my full statement be submitted for the record.

Chairman THOMPSON. It will be made a part of the record.

Thank you very much for being here today, gentlemen, all of you. It looks to me like in getting back into this again this year and looking at the statements and so forth that, once again, we risk those of us who are proponents of this legislation and those who are opponents, some risk of talking past each other. Those who promote this legislation want better rules, and those who oppose want to do nothing to make things less safe or less healthy, as if these were two different positions.

I think the main point that I would like to make out of all of this is that better rules will make for a safer environment. We live in an age of regulation. Some people think the more regulation, the

better. It is especially better if it is unquestioned and we set up a regulatory that essentially does not have to give any reasons for what they do. I disagree with that.

But the fundamental question is, what is most likely in the long run to produce a safer environment, a healthier environment? Is it one where the best science is used or not used? I mean, we worship at the altar of science in this country and we have made tremendous strides in our ability to do such things as risk analysis, for example. Yet we have to ask ourselves the question, are we better off if we avail ourselves of that or not? Are we likely to produce a safer or healthier society by analyzing?

Those are the key words of this legislation, analysis, assessment, balanced review, having experts look at it. Are we better off? Are we going to be less healthy or less safe by having an assessment of what we are doing, by having experts balance all views presented, looking at it?

We know that we are spending more money than we need to. Every expert in the field will tell us that, billions and billions of dollars. We know we do not always come up with the best regulations. We know we do things sometimes that, contrary to the best intentions, hurt people instead of helping people, whether you talk about air bags or asbestos removal or drinking water standards and so forth. Oftentimes, we know we do not have the right priorities, that we are using limited resources in ways that somebody thought was the best way to use it, but unquestioned, unaccountable, basically, not transparent.

So which is most likely to produce a safer, cleaner society, that way or using scientific benefits that we have derived over the years in the framework of analyzing it and assessing it and doing a balanced review?

The irony of it to me is that when people talk about, well, it is going to slow down the process and all the bad things about this and so forth, is that under the President's Executive Order, in most cases, we are supposed to be doing these things anyway, cost-benefit analysis and that sort of thing.

So we really are perpetrating a fraud when, on the one hand, we say we are doing it while we know that, apparently, in many cases, we are not doing it. We have it on paper because we give lip service to the notion that these obvious things are true, and that is we are better off if we bring some of these things to bear. We give lip service to that. We put it in writing and we put it out there as a good thing to do, apparently not thinking that it is going to slow down the process, not thinking that it is going to produce a more dangerous or less safe society. But then we want to be free to totally ignore that.

It does not make sense to me. It looks to me like we are better off in the long run to bring these other things to bear, and again, as Senator Levin said, without even requiring—this is informational. This has to do with analysis of what we are doing and assessing what we are doing, reviewing what we are doing. Is that really going to produce a more dangerous society? Is that going to make our children more susceptible to E. coli, by using the limited resources that we have for things that will, with better informa-

tion, be directed toward where the problem is and having someone unaccountable essentially doing that?

Mayor and Mr. Roberts, you deal where the rubber meets the road, and the mayors and States and so forth, as you point out, Mr. Roberts, most of this is done at the State level. As Director of the Environmental Council of the States, you represent the people who do the environmental work there. You obviously have to be concerned about the claim that what you are advocating here is going to make a more dangerous society, you are somehow endangering the health of the people that you represent. What is your response to that?

Mr. ROBERTS. Mr. Chairman, I think it goes without saying that no State environmental department sets out to endanger the health of the people in the State. No administration, no governor is interested in anything remotely approaching that.

Our position has been that the more that rules are scientifically based and cost based and the more we have tools to make those kinds of decisions, the better we can target the limited resources that are available, and resources are always going to be limited irrespective of what their total amount is. We can spend them more intelligently on more pressing problems.

The more rules are easily understood, the more the public will support them. The more people are involved in the making of the rules, the more people will buy into the rules and support them. So these seem to us to be two tools in a broad range of public participation to make better, more targeted use of resources in dealing with more pressing and immediate problems.

Chairman THOMPSON. Mayor Lashutka.

Mr. LASHUTKA. Mr. Chairman, Members of the Committee, the question you raise is a legitimate one. Frankly, my colleagues across the country, I think, are as environmentally sensitive as anyone because their constituents understand that for the young and the old and those of us in between, that in our cities if we do not protect the environment and if we do not provide a quality of life, people will leave. They have the idea of moving to other States and other cities. We want to keep our businesses. We want to keep a quality of life that is very important.

We have a choice of either complying with all of these regulations and raising the cost of doing service, either as businesses or taxes we impose upon our citizens, or stretching those dollars as long as we can. Two examples might be helpful. I am afraid sometimes examples, though, polarize on both sides, so I do not mean that. That is not intended.

But the unintended consequences that were a concern came from a regulation in Columbus on a chemical for our water treatment plant that, to the best of our knowledge, was used only for pineapples in Hawaii. We do have a very aggressive and growing agricultural community that is part of central Ohio, but growing pineapples is not part of what we make in central Ohio as part of our agricultural effort. And so those dollars could be better used for——

Chairman THOMPSON. Tell me exactly what you are talking about here. What was the regulation and what was the——

Mr. LASHUTKA. This has been cured subsequently, but it was used roundly on the unfunded mandates legislation that talked about the unintended consequences and the problems, but before that was passed, we were required in our drinking water statutes to test for a chemical that is only used for the growing of pineapples and that is primarily in Hawaii. That was not the intent. I think good people tried to have a regulation, but it goes back to the "soda straw" example.

On the flip side of it, we also saw a blip in our lead testing which occurred randomly in the spring on water runoff. We have been tested by both Ohio Environmental Protection Agency and the U.S. Environmental Protection Agency, and the Senator now from Ohio who was governor then and I talked about it, but the regulation required us, because of the time frame, to send a notice to all water users who provide water users in our city and the entire region. I know I have a legitimate lead paint situation on the south side of the city with older houses. The dollars used for that mailing, which could have been mailed in a regular water and sewer payment, had to be mailed separately because of the Federal regulation and we could not until a year or two later have a reach in our stretch of dollars for a legitimate effort in the south side housing effort on our lead paint situation.

That tradeoff, we make every day, and we have to make those and we are forced to. But we clearly think that this legislation, as has been said by my friend, Mr. Roberts, will be more informational, provide a better result, and frankly, maybe in some occasions, slowing it down is in everybody's best interests. When we need to move ahead, we are willing to do so in the interest of safety of our people, just as those of the Federal Government.

Chairman THOMPSON. You say slowing it down might be in some cases be in everybody's best interest. What are you thinking about? In what kind of situation?

Mr. LASHUTKA. Let me move away from the environmental side, but recently, there was a regulation that came out of the Department of Housing and Urban Development and the rule would have granted HUD unilateral and unbridled and unchecked authority to determine whether a city or a State could curb the efforts regarding fair housing, both within and outside of our legal authority. It was criticized roundly without any input meaningfully from those of us at the State and local level.

I might give the good side of the story. It was reviewed after a hue and cry came from those of us responsible and HUD retracted that order, but if this legislation was in place, it would have compelled that discussion before unintended consequences provided an adverse result, another example of something that did not work but was intended to be a good result. It just did not fit with the way people are regulating in the real world.

Chairman THOMPSON. Thank you very much. Thank you, gentlemen.

Senator Lieberman.

Senator LIEBERMAN. Thanks, Mr. Chairman. Thank you, gentlemen, for your thoughtful testimony.

Let me go back, if I may, to the contrast I tried to draw in my opening statement between the targeted regulatory reform that has

been part of, for instance, the Safe Drinking Water Act Amendments, and the broader regulatory reform that is involved in S. 746, about which, as I have said, I have concerns of what I have called unintended consequences.

Let me ask you specifically to comment on the concern I expressed about the possible impact of this legislation if it were adopted on those sections of the Clean Air Act Amendments of 1990 that control toxic air pollution. My concern is that this legislation, S. 746, would require risk assessments in this program, the toxic air pollution program, where Congress decided in 1990 that analysis of risk would no longer be required. What might potentially happen here is that we would end up in a quagmire of delay that Congress intended to avoid in 1990.

So my question is, to any of you or all of you, why does it make sense for us now to make a decision that would alter the decision we made in 1990, that the problem was so severe with this limited number of chemicals that we did not need to wait for risk assessments? For instance, we have not studied the circumstances involving the regulation of air toxics anymore in coming to the consideration of this bill. So that is my concern. Why adopt a bill that might well overturn a judgment that we made earlier, in 1990? Does anybody want to take a shot at that? Mayor Lashutka.

Mr. LASHUTKA. Senator Lieberman, Members of the Committee, I would like to, and this may not be totally on point but I think it generally is in the ballpark.

Some years ago in this country, there was a huge concern that landfills were a dramatic problem, a concern identified at the national level and one at the local level. In the six priorities of reduce, reuse, recycle, there were landfills and waste energy as the next two and then through a discussion, landfills dropped to No. 6 in that priority.

In the meantime, our community under a prior mayor concluded that landfills probably should not be the preferred choice because they were tough to site, they had environmental problems, and we were encouraged through policy then to pursue a waste-to-energy plant, and we did, popular in Europe, growing in some discussion in this country. At a cost of several hundreds of millions, we created a cutting-edge facility. It had problems, but overall was performing, the biggest recycler, I might say, in our area.

During my time as mayor, I inherited this facility, but a curious thing happened. Landfills then moved back from No. 6 to No. 4 as a preferred choice. Waste-to-energy plants, because of issues that would be a concern on air pollutants, became less desirable, and we were closely scrutinized, as every waste-to-energy plant all across America.

And over the back of that, I had to appoint a board to a regional authority that the governor and others in the legislature thought was appropriate so we could regionalize our approach. That board was faced, as we were as owners of the facility, with criminal sanctions if we did not succumb to what was perceived as a threat by Dioxin. After all, that was a challenge. Most of the people I appointed, who are good citizens, business people in our community, people who are concerned about the environment, chose not to have to go to jail to pursue this issue and it was settled.

Oddly enough, without much discussion nationally, the issue of Dioxin, which was going through some significant challenges on peer review, dropped off the chart and was not the threat that it was alleged to be at the time we had to face criminal sanctions in keeping the plant open.

Consequently, it is closed. We are picking up off of our general obligation debt the funding for the bond holders, and we still have a AAA bond rating in spite of that, and the threat that was perceived, without having appropriate peer review, went away. Somehow, in our citizens' confusion, this is a significant question. How could all of this happen?

Now, if the threat was not legitimate at the beginning and it ultimately left with huge consequences, and luckily, we are a robust city financially, we could endure it. But for other cities going through similar consequences, these are back breakers, and particularly that 75 percent of our smaller cities who are dealing with well intended consequences but they do not comport to the real problems with cities.

I hope that is somewhat helpful to you as a legitimate problem in our city.

Senator LIEBERMAN. Yes, I hear you. It is interesting, the response. My concern is that in this case, there has been no similar change of attitude or evidence regarding the air pollution standards.

Incidentally, I want to tell you that the robust nature of your economy, I believe that my 11-year-old daughter takes partial credit for because of her excessive purchases from the Limited Too.

Mr. LASHUTKA. The chairman of the Limited Too, all the stockholders, and I appreciate your daughter's buying and we would encourage more, of course, in your discretion with you and your wife.

Senator LIEBERMAN. Thank you. I have another question, unless either of you is eager to jump into that one.

Mr. Roberts, let me focus another example of my concern to you because it involves State activities with regard to automobile tailpipe emissions and standards that some of your member States have taken in trying to achieve cleaner ambient air. In establishing, as you know, the ambient air quality standards, EPA conducted fairly broad analysis of health benefits and risk reduction, but in developing the automobile tailpipe regulations needed for the States to achieve their ambient air quality standards, EPA analyzed their effectiveness in meeting the standards but did not repeat the analysis of health benefits and risk reduction.

So my question is whether you have considered whether S. 746 might cause delays in establishing tailpipe emissions standards by requiring EPA to go back and reanalyze the underlying risks of violating the ambient standards and the health benefits of achieving them.

Mr. ROBERTS. Senator, we have not looked at an impact like you describe on any existing program, and certainly I would never tell you that there is no possibility of unintended consequences of any legislation that might come out on this subject. In answer to your first question, we have not looked at the impact on the clean air, either.

Senator LIEBERMAN. Right.

Mr. ROBERTS. As I said before, I think our position is simply that these are additional tools to be applied to help us spend limited resources more effectively. I do not understand the bill to go back and require relooking at prior decisions that have been made, but I could be wrong in that interpretation.

My concern about a targeted change would be, as you know, the great difficulty in considering the major environmental legislation a piece at a time, as in the reauthorization process. That can be very time consuming. To take that approach delays what we would see as the benefits of this kind of an approach.

Senator LIEBERMAN. I wonder if I might ask you—if it is something that you can do without spending too much of your time—if you might raise the question I raised with some of your member States. I would appreciate hearing in writing what their reaction is.

A final question, which goes to another example of the kinds of concerns I have. Currently, EPA and OSHA do not conduct risk assessments for right-to-know regulations, which, as you know, provide communities and workers just with information about toxic chemicals and releases, and they have had a generally salutary effect. I think even the businesses involved have a pretty good feeling about the effect now.

The community right-to-know law, for example, requires companies to let the surrounding community know the amount of certain chemicals that are emitted from a facility. There is no requirement that exposure data be collected. It is just informational, and the hope is that you put people on notice and maybe, by the fact of disclosure, you encourage the source to reduce the emissions. But there is no mandate in there.

So my question is why a risk assessment and cost-benefit analysis should be required for a regulation like this one that does not control toxic exposure but instead just mandates public information. Any response?

Mr. ROBERTS. I think, Senator, the response to the requirement to release the information has generally been what you alluded to, and that is that the releases have been decreased——

Senator LIEBERMAN. Yes.

Mr. ROBERTS [continuing]. Simply because people did not necessarily want to be branded, if that is the right word, with having made those releases.

Senator LIEBERMAN. Right.

Mr. ROBERTS. And so in that instance where the requirement is a public information requirement, it would seem to be having the salutary effect that was desired, which was to reduce the releases themselves.

Senator LIEBERMAN. It is, indeed, and my concern is that, notwithstanding the general support for the law at this point, that S. 746 would subject it to regulatory review and risk assessment and cost-benefit analysis that might delay or defer its effectiveness.

Mr. ROBERTS. I will ask those questions as you asked, Senator, and will reply to you in writing.

Senator LIEBERMAN. Thank you very much. Thank you, Mr. Chairman.

Chairman THOMPSON. Thank you very much. Senator Voinovich.

Senator VOINOVICH. Mr. Chairman, first of all, I think that your statement was well taken in that what we are talking about here today is something that appeals to common sense, and that is that if you are going to pass a rule or regulation, and we are talking about rules and regulations that are over $100 million nationally, that you ought to use risk assessment and cost-benefit analysis to determine whether or not the regulation is, indeed, needed.

In addition, I think that people should be comfortable with the fact that OMB and the Office of Science and Technology Policy would be the organizations to establish the objective criteria by which you go about making those decisions, which would, I think, be very helpful to our various Federal agencies.

In addition, I think, in response to Senator Lieberman's questions, S. 746 does not override statutory standards nor statutory deadlines that are currently in effect today. So those are exempted from this legislation.

It also does one other thing that I think is very important and I think was part of the compromise that we put together last year on this legislation, and that was that it exempts rules where the agency finds for good cause for proceeding quickly without complying with S. 746. So there is a provision that says that here is something that is very important and for just cause, we are going to bypass S. 746 and get out there and take care of that situation.

In terms of the tailpipe issue that Senator Lieberman brought up, it is very interesting. Ohio is one of the few States that have instituted emissions testing, and as Mayor Lashutka knows, I caught a great deal of hell from a lot of people for instituting it. By the way, today, we have every area in the State but one that complies with the current ambient air standards.

But one of the things is that a lot of groups raised the issue about whether or not tailpipe emissions testing really does something to help the air. We went back to the EPA, and you know something, they did not have the scientific data to prove that it did, and so we got Congress to appropriate last year $350,000 to do a study for the EPA to verify the fact that, indeed, this does make a difference on the environment. So we are trying to get at stuff that, from a common sense point of view, makes sense, and I would have loved to have been able to say to them, hey, the science says this really does work. They had not done that.

I would like to ask Mayor Lashutka, and this is a little off the subject, but I am going to ask it anyhow because I wanted the Chairman to include this in this bill and he is going to do it some other way, you and the "Big 7" worked hard to ensure that Medicaid was covered by the Unfunded Mandates Reform Act of 1995,. However, the Congressional Budget Office is misinterpreting the mandates law in a way that takes most Medicaid mandates off the table.

Chairman Thompson has led the charge to correct CBO's interpretation, and last year he introduced S. 2068, a bill that was cosponsored by Senator Glenn, my predecessor. This legislation made it clear that cutting the Federal share of Medicaid and requiring States to make up the difference is, indeed, an unfunded mandate. I am working with Senator Thompson to reintroduce this bill in the

106th Congress and I would like to know, does the "Big 7" have a position in regard to this legislation?

Mr. LASHUTKA. Yes. Mr. Chairman, Senator Voinovich, I believe the position is in support of that bill. That legislation is consistent with the spirit of the debate that took place in the unfunded mandates legislation that was successful again in 1995 and we think that amendment will be helpful to States and local government.

Senator VOINOVICH. Thank you.

Mr. Roberts, some argue that Federal agencies are already required to conduct risk assessment and cost-benefit analysis under Executive Order 12866. If they are required to do so, why is this legislation needed?

Mr. ROBERTS. Senator, we are not certain that those analyses have always been done as they were required to be done. This would strengthen the requirement that such analysis be done before the rule is finalized. It would institutionalize a way in which State and local government officials might be able to participate in that process before it was complete and we would regard both of those as advantageous to those agencies that are carrying them out on a day-to-day basis.

Senator VOINOVICH. I think one of the things that all of us are concerned about in terms of rules and regulations, also, are that dollars be spent that really make a difference in terms of the environment, and I think that, getting back to my example about tailpipe emissions and the inconvenience and the cost of it, it is nice to know that, whether you are a businessman or a governmental agency, that the costs that are incurred as a result of what you are being asked to do really do make a difference. That makes it a whole lot easier.

In addition, I think that from a point of view of public safety or environment, with dollars that are limited, you want to make sure that when you do spend those dollars, you are spending them on those things that are really going to make a difference and not put them on something that may be the flavor of the month and you get into it and you get back later and realize that you have invested the money and you are not getting your return on it, whereas you could be spending that money on something else and really making a difference in terms of public safety or the environment or public health.

Mr. Chairman, I am finished.

Chairman THOMPSON. Thank you very much. Senator Levin.

Senator LEVIN. Thank you, Mr. Chairman.

Senator Voinovich raises a specific issue which actually had an application in Michigan on the tailpipe emissions. Ours was very similar and it illustrates what this bill is really all about.

On the west side of our State, we had three counties that were required to go through testing of each automobile, take certain action on each tailpipe, because the three counties had, I believe, 2 or 3 days a year of excess ozone. The reason they had excess ozone in those three counties was because of certain air that was blown up from the south. It came up from Indiana, Illinois—but in any event, from the south. Let us leave it that way.

Chairman THOMPSON. But not too far south.

Senator LEVIN. Yes, just the right distance. [Laughter.]

I think we lost Durbin to this cause already. I cannot do any more damage.

Senator VOINOVICH. You may have lost me. [Laughter.]

Senator LEVIN. I think I will actually gain you on this. I cannot get more support from you than we have already received.

Now, EPA then forces every person in those three counties to take an action which is totally irrelevant to the air quality. If there were no cars in those three counties, you would still have the same number of days of violation. You could push all the cars into Lake Michigan.

EPA then became a subject of scorn. People were put to expense and trouble to do something (putting aside the fact that they did not cause it, forget that) to do something that they cannot correct. Two things happened, and I think, Mr. Roberts, you and others here already said so. Money was wasted that could be used for a good cause and public support for environmental protection, through that particular agency, at least, is undermined. Both those things happened. Was the environment advanced by that? That was the purpose of it. It had the opposite effect. That is our tailpipe experience on the west side of Michigan.

First, let me ask the mayor, in your judgment and in the judgment of the League of Cities, will this bill in any way harm the environment or public safety?

Mr. LASHUTKA. Mr. Chairman and Senator Levin, no.

Senator LEVIN. Mr. Roberts, you have described briefly the work that you do and I would like you just to explain a little bit more. You have given us some very good figures in terms of the percentage of certain activities which are carried out by the States and so forth. Are the States that you represent, States and territories, all but, I believe, two or three, you said?

Mr. ROBERTS. Yes, sir, 52 of 55.

Senator LEVIN. The agencies that you represent, the heads of those agencies are responsible for protecting the environment in those States, is that correct?

Mr. ROBERTS. Yes, sir. They are in most instances appointed by the governors of the State and confirmed by some element of the State legislature. In some instances, they work for commissions that have been appointed by the State. But in all instances, they are responsible for carrying out the Clean Water Act, the Clean Air Act, RCRA, CRCLA, those kind of pieces of legislation, and they are, with the exception of the governor, the only official in the State that is responsible for all elements of environmental protection within the State.

Senator LEVIN. Senator Lieberman suggested that the bill overturns Congressional mandates or intent, and I do not believe that it does. I agree with what Senator Voinovich said on that. For instance, Congressional direction to use the best available technology or the maximum achievable technology is not affected by this bill. This bill adds information where a problem is to be addressed by an agency. And, by the way, I think the other example you used would also not be covered, since the information requirement in terms of the toxics which are released into the air does not require any action. It is simply an informational requirement.

Ironically, that is what this bill does. It is a wonderful example of a way where information can lead to a result, even though it does not mandate a result. I think that the bill requiring the listing of toxics that are released into the air has had an impact without mandating anything other than information. That is what this bill is all about. So, ironically, that example, I think, is supportive of the approach used by this bill.

But in terms of your specific point, because the requirement does not address a problem by requiring an action to be taken relative to it, it does not mandate anything, it is my belief that we can work this out, and that this bill's requirement would not affect that particular Congressional intent.

Just one final question, Mr. Holman. You have given us a very interesting example in your toxic sand. As I understand that example, you had a situation where there was a certain percentage of sand which could be toxic as a byproduct of your processing, your manufacturing process, and that you were required to handle it in a certain way which was more expensive than how you could have handled that in a different way.

The issue, then, is not whether or not, as I understand it, you are going to address the problem of the byproduct. You believe that that problem should be addressed. The issue is whether it needed to be addressed in the more expensive way required by the Federal regulation or whether or not you would be permitted to address the same problem in a less expensive way. Is that generally correct, and if not, just correct me on it.

Mr. HOLMAN. The sand has binders in it and certain processes have binders that can produce some toxic by the standards of the EPA. Most of the sand is not. Most of the foundries use binders that do not create that. The point is that we have been forced to treat all sand, that 90 percent which is not toxic, the same as if it were toxic.

Senator LEVIN. Well, now how do you know without treating it that 90 percent sand is not toxic? How can you be so confident? Do you not have to treat it all in order to cover the 10 percent?

Mr. HOLMAN. Because of the process that you use. For example, you know what binders that you are using in the sand or that you are buying for that particular process. If you are not using that binder in your foundry, you know that you do not have that problem.

Senator LEVIN. All right. So you are being required to treat a byproduct of a process which does not use a binder which creates the problem?

Mr. HOLMAN. That is right. So they are broad-brushing all sand with those foundries that use, for example, phenolic binders which may require toxic handling with other binders that do not require that.

Senator LEVIN. All right. And that has an impact on your costs?

Mr. HOLMAN. A tremendous impact on the costs. It is trucking, disposal costs, when it could be used for a resource. We ought to get paid for it, not have to pay to get rid of it.

Senator LEVIN. When you say paid for it, because you could use that in another——

Mr. HOLMAN. As a resource, right.

Senator LEVIN. But it has a cost, an expense that you must incur to which is useless? It increases the cost of your product?

Mr. HOLMAN. It increases the cost of the product.

Senator LEVIN. Does it make you less competitive?

Mr. HOLMAN. Absolutely, on an international market.

Senator LEVIN. It costs jobs, wastes money, no environmental benefit, is that a fair summation?

Mr. HOLMAN. It is a fair summation, and it uses up landfill space.

Senator LEVIN. Indeed, has an environmental detriment.

Mr. HOLMAN. That is right.

Senator LEVIN. So something which is intended to have an environmental benefit is an environmental detriment, costs us money which we could use for the environment or public health, safety, welfare, and makes you less competitive, which then costs us jobs, costs you, obviously, as a small business person, money and profit.

On the international market, do you know what other countries would require their small business people to go through that same process? Offhand, would you know if any other country does that?

Mr. HOLMAN. I think the only country that I can think of perhaps is Canada, but——

Senator LEVIN. They might?

Mr. HOLMAN. They are not a major competitor of ours. We are dealing with overseas competitors.

Senator LEVIN. Have you talked to your Canadian colleagues and asked them if they have the same problem with their regulation? I am curious.

Mr. HOLMAN. No. I have not talked with them.

Senator LEVIN. Have we lost significant business to countries which do not have that requirement?

Mr. HOLMAN. Absolutely, and I am talking about India, South Africa, the Czech Republic, all of the overseas—we compete internationally, as do many metal casters.

Senator LEVIN. Thank you. Thank you, Mr. Chairman.

Chairman THOMPSON. Thank you very much. Senator Durbin.

Senator DURBIN. Thank you, Mr. Chairman. I want to thank the panel for being here.

I want to follow up on that last question. It really raises an interesting challenge to us, since we are in the world of global competition, but I think we also have to concede that there are certain standards of living in America that we are very proud of, the quality of our clean air and clean water, the protection of our citizens when it comes to environmental standards.

If we were to be asked to compromise those to be more competitive in the world market, I think most American families would react negatively. They would say, surely, in our ingenuity and creativity, there must be a way to be competitive without in any way endangering the water I drink or the air that I breathe. So I hope that the global competition argument does not suggest that we have to go down to the lowest common denominator.

I have visited China. China is coming on. It is a huge economy and everybody is interested in it and it is going to be producing a lot. I can tell you that any time of the day or night that you get up in Beijing, you will face fog. That fog is pollution. It is there

when you wake up in the morning, it does not burn off at noon, and it is there when you go to sleep at night. That fog and pollution comes from burning coal. We certainly do not want to accept standards at that level to be "competitive" in the world economy.

I do not quarrel with your statement, Mr. Holman, nor Senator Levin's that there are regulations that go too far, but I think we have to keep a perspective here about the fact that, yes, in America, we will do it a little differently. We will make it a little tougher for business because we believe that that is part of the quality of life in this country.

I would like to ask the mayor here a specific question, though, because I want to go back to an illustration he used. I do not know much about toxic sand, so I cannot really follow up there. But I really do want to address the issue about pineapples in Ohio, if I might, because I thought that was an illustration that was given and has been mentioned before about just how silly regulations can be, the idea of checking for a chemical that is being used to grow pineapples in Ohio.

Yet, when you look more closely, it turns out that there is much more to the story. I am going to mispronounce this, but I am going to try. The name of the chemical, DBCP, is dibromochloropropane. It is a highly persistent pesticide that, in fact, has been found in ground and surface water across America. It was widely used as a soil fumigant across the country on over 40 crops until it was outlawed for most uses other than pineapples. DBCP is considered a probable human carcinogen. It has been linked to sterility in production workers. Therefore, it was restricted from most uses in 1987.

Due to its persistence, it has been found in 16 of 25 States that have tested for this pesticide and at levels that exceed EPA's drinking water standard in at least 10 States. Over 2,000 wells in California alone are contaminated with DBCP. This is a report from 1995.

The cost of testing contaminants in intake water under the Safe Drinking Water Act had been wildly exaggerated. EPA estimates that, aside from testing for bacteria and lead and copper from pipes, the total nationwide testing cost is $60 million per year.

The reason I raise that, mayor, is that there is always more to the story, and although this pesticide is used on pineapples, it clearly was used by a lot of other people for a lot of other reasons, and that may be the reason why you had to test for it in Ohio, and probably in Illinois.

I can understand that government can go too far, and maybe the toxic sand example is an illustration, but do you not agree with me that once you have heard the whole story, that perhaps picking out this pineapple pesticide really does not tell the story completely?

Mr. LASHUTKA. Mr. Chairman, Senator Durbin, I have heard nothing from you that would dissuade me that my argument is incorrect. There is no evidence of a problem in central Ohio. Your reading does not suggest there was. And, in fact, it was an illustration, I think, that held the test of time then for us and does today.

I have agreed that there are extreme examples that do a disservice to both sides of this argument. It was not my intention to do so. I think it fits more into the example that my friend, Mr. Hol-

man, said about a well-intended consequence that was blanketed for everybody without pinpointing where those problems are that should be part of the mission of the State environmental protection agencies and U.S. EPA.

Clearly, a mayor in California with the evidence problem would do the same thing. They would test on water quality. What you read to me did not suggest anything that that problem exists in central Ohio, and yet I am required then to have tested it.

Might I say that that has been corrected by U.S. EPA in the interim as we had the debate on the unfunded mandates legislation, and it is to their credit they recognized that perhaps it was overreaching, as well. At least, that is the understanding I have from my folks who run our water treatment plant, and it shows a willingness when more information is provided that we have the ability to adequately regulate and wisely regulate.

So, no, I would not agree with your conclusion there at all. I do not shift my——

Senator DURBIN. Well, let us just go a step further.

Mr. LASHUTKA. Sure.

Senator DURBIN. If you have a chemical that is a known carcinogen and that has shown up in States across the Nation—let us see here, now, 16 out of 25 have been shown to exceed the EPA's drinking water standard and at least 10 of those States—you do not think we should test for that?

Mr. LASHUTKA. That is not what I said. I will repeat what I said to make sure that you and I are communicating appropriately. What I have said is that if there is evidence of a problem——

Senator DURBIN. That is fair. I agree with that.

Mr. LASHUTKA [continuing]. And what you are saying——

Senator DURBIN. Are you sure there was no evidence of it in the State of Ohio?

Mr. LASHUTKA. I did not say that. My city is in central Ohio. We have a region that has seven cities with a population of 100,000 or more. The problems in Columbus are different than they are in the industrial belts that include Youngstown and Cleveland. We are agriculture, primarily, and service, with some industry. Cincinnati and the river has a different set, and frankly, that is the spirit of what this legislation is all about, is to have information, have it risk based, and address those problems legitimately.

Senator DURBIN. I think it is reasonable, I would agree with you, that if there is no evidence of this chemical in the State of Ohio, to put that standard is not reasonable. There has to be some connection. But I want to make the record clear that it has a lot more to do with a known carcinogen than growing pineapples. I hope that we can both agree that if there was evidence in my home State of Illinois or yours of Ohio, we would want testing, would we not?

Mr. LASHUTKA. There is no question, if there is a legitimate problem, I think that there is a responsibility for mayors, for regulators at the local and the State and the Federal level, and more importantly, I think those people who are residents and run the businesses all want the same goal. But it is not blanketed. It should not be viewed that all parts of Ohio are the same or, frankly, all parts of Illinois the same and that regulations that affect Chicago

are the same thing downstate in Illinois or they are in Columbus versus the other parts of our State.

Senator DURBIN. Mr. Roberts, may I ask you a question. Going back to Senator Lieberman's question, we passed a law that said if you are a business that would emit certain chemicals which we considered unsafe, you would be required to report that emission so that people in the local community would know that you and your plant were emitting these chemicals into the atmosphere. It is known as the Toxic Release Inventory.

Getting back to this whole question about cost-benefit assessment, there clearly is a cost to the industry involved here. They have to report it and probably have to file a lot of forms to do it and hire some people to make sure it is done right. How would you measure the benefit to the public and their right to know that those chemicals were being emitted?

Mr. ROBERTS. First, Senator, I do not know whether that requirement, if it came along now, would be subject to this bill or not, and that is just lack of understanding on my part. I do not know whether this requirement for the cost-benefit analysis would apply to the Toxic Release Inventory if it came along now and it is one of the points that we have indicated we will try to respond in writing to Senator Lieberman about.

It is very difficult to measure the benefit there. I agree with you, absolutely. What has happened, as we have noted already, is that most of those releases have been reduced simply because the industries or factories involved did not want to be associated with that maximum release.

Now, in that current legislation, all that is measured is release. Exposure or impact is not measured, and if there were a way to measure the exposure or impact that could easily be applied, that would be a better measure than the release and it would be headed in the direction of this legislation because it would be a measure of the risk of that release. But I agree with you that it is very difficult to measure what the benefit would be.

Senator DURBIN. But I want to follow through, because I really think you get to the heart of this legislation with the answer you have just given to me. You cannot quantify the value of the public right-to-know. How do you put a dollar amount on that? I think that is what you said. But I think what you also said, you could quantify illnesses or deaths associated with it.

We believed in passing this legislation that there was a social value to public information, that mayors, governors, Senators, Congressmen would know that these chemicals are being emitted, perhaps to give notice to some agency to more carefully track, to perhaps suggest that maybe in Columbus or Springfield, Illinois, that the emission of these chemicals might have a possible impact on groundwater and the drinking water of people who lived in the mayor's town or my town.

So, you see, that is where I have a problem with this legislation. You cannot put a dollar sign on everything, and trying to put a dollar sign on the public right-to-know, I think, really raises a serious defect in this bill.

Mr. ROBERTS. I do not disagree with what you are saying, Senator. The only addition I would make is that Congress, State legis-

latures, State environmental agencies, mayors, city councils, all are driven to make decisions about where to spend their resources, and recognizing the limitations of this kind of analysis, if it can help make those decisions, we would be in favor of it.

Senator DURBIN. Thank you for your testimony. Thank you, Mr. Chairman.

Chairman THOMPSON. Thank you very much.

On the Toxic Release Inventory question, the TRI rules do not have the primary purpose to address, that is treat health, safety, and environmental risks. TRI rules simply require the disclosure of emissions information. Therefore, S. 746 would not require risk assessment for the TRI rules.

Insofar as cost-benefit analysis goes, S. 746 would only apply that requirement if the Executive Order would require it. It is our understanding that TRI rules typically have not had an impact of $100 million annually and thus has fallen under the requirement for cost-benefit analysis under the applicable Executive Order. Since S. 746 contains the same basic provisions for applicability of the Executive Order, it cannot really be asserted that this legislation will apply where the Executive Order does not.

I believe that is the appropriate answer to the question as far as the right-to-know regulations are concerned. It is just not what this legislation is designed to affect.

Unless anybody else has——

Senator LEVIN. I just had one comment, one very quick comment.

Chairman THOMPSON. Go ahead.

Senator LEVIN. I could not agree more with Senator Durbin, that you cannot put a dollar sign on everything and that you surely cannot measure a child's health in dollars. This bill does not. Let me just say it again. This bill does not. The bill says it six times. I am not going to say it orally six times. I just said it twice. But I could not agree more that you cannot measure health, or life, in dollars. Now, there are some efforts on the parts of some people to do that, to attach the value of a life, some of the scientists do try to do that. This bill does not—this bill uses both quantifiable and non-quantifiable benefits.

I think it is so important that we put that off the table. There are a lot of important issues that this bill tries to address, but it does not put a value on a human life. If 10,000 fewer kids are going to be asthmatic because of some regulatory action, that is a valuable fact to know. You do not need to specify the value in dollars of having 10,000 fewer asthmatic kids. Those benefits may be non-quantifiable.

Senator LIEBERMAN. Mr. Chairman, I just very briefly want to put on the record my own—I do not know if I would call it a dissenting opinion—but an expression of uncertainty about the interpretation of the applicability of S. 746 to the Toxic Release Inventory, for instance. And just to read from the bill, it says that "each agency shall design and conduct risk assessments in accordance with this subchapter for—(i) each proposed and final major rule the primary purpose of which is to address health, safety, or environmental risk."

So I would argue that a Toxic Release Inventory requirement is a rule which has the primary purpose of addressing health, safety,

or environmental risk, even though it does not mandate any behavior beyond the release of the information. But perhaps that will be settled by a higher court sometime.

Senator LEVIN. Actually, it could be settled by the sponsors of the legislation, who have both just spoken out on it today. The word "address" means treat. But in any event, as the two lead sponsors of this legislation, we have just said that that is not the intent. We do not think that is what the word means. So that should not be a problem in terms of clarification.

Chairman THOMPSON. I think that is true. My only parting comment would be, with regard to the quantifying human life and so forth, it is ironic to me that those who would want the status quo and put all your trust, faith, and confidence in an unsupervised kind of regulatory situation, but at the same time think that if we pass this law, that those same people would be in some way minimizing the loss of human life or that if you look at any of these major rules with regard to teen smoking or tobacco sales to children and things like that, the benefits greatly outweigh the costs.

So these same people are not going to change their stripes overnight and start minimizing or discounting or in any way upsetting the balance as far as what traditionally have been the assessments of costs and benefits. Any of those things, as far as I have seen, where you have got public health issues, kids smoking or the meat inspection rules or anything like that, the benefits clearly have always outweighed the costs in those assessments and I would assume that they would continue to do so.

Senator DURBIN. Mr. Chairman.

Chairman THOMPSON. Yes, Senator Durbin?

Senator DURBIN. I was going to suppress the urge to comment again, but since you raised the issue of tobacco, I have to tell you that that is a classic illustration of why this does not work. This Dutch survey that came through and said stopping people from smoking allows them to live longer and cost us more, if they continue to smoke and die an early death, they are cheaper, just to put a cash register up on the table and measure it, you would draw a conclusion, well, maybe we should not stop people from smoking. But, thank God, we did not draw that conclusion. We are trying everything we can and 41 State attorneys general are trying to stop them, too. Just measuring it in dollars and cents does not work sometimes.

Chairman THOMPSON. The FDA, when they looked at it, they put, as far as tobacco sales to children, they put the benefits at between $28 and $43 billion a year and the costs at $149 to $185 million a year. They did not look at it in the same way that you are looking at it.

I would just simply say that, again, these regulators who we place our faith and confidence in and the opponents of this bill do not want to upset that, I would suggest when they take a look at that situation that it is going to be a no-brainer. They will not say, oh, my God, because somebody has done this analysis, we are going to have to not regulate in this area. We are talking about non-quantifiable benefits as well as quantifiable and non-quantifiable costs. We have a provision in there that says if it is contrary to the

public interest, the law does not even apply, every safeguard imaginable.

So, again, we have either got to have some confidence in our regulators or not. We cannot have it both ways, I do not think.

But anyway, gentlemen, thank you very much. We have got another panel here, so we will not detain you any longer. You have been very helpful to us and we appreciate your comments. Thank you.

I would like to turn now to our second and final panel. With us today is Professor Ron Cass, Dean of the Boston University School of Law and Melville Madison Bigelow Professor of Law. Dean Cass is also Chair of the Section on Administrative Law and Regulatory Policy of the American Bar Association.

He will be followed by Dr. Lester Crawford, Director of the Georgetown University Center for Food and Nutrition Policy.

Our third witness will be Dr. John Graham, Director of the Harvard Center for Risk Analysis.

Pat Kenworthy will then testify on behalf of the National Environmental Trust.

Our fifth witness will be Frank Mirer, Director of UAW Health and Safety Department.

Dr. Mirer will be followed by David Vladeck, Director of the Public Citizen Litigation Group.

Because this is a large panel, I would like to again encourage the witnesses to limit their oral testimony so that we can give ample opportunity for questions. Your prepared testimony will be included in its entirety in the record.

Dean Cass, would you like to begin, please?

TESTIMONY OF RONALD A. CASS,[1] DEAN, BOSTON UNIVERSITY SCHOOL OF LAW

Mr. CASS. Thank you, Mr. Chairman, Members of the Committee. I appreciate the opportunity to appear here.

Let me just make three brief points about this legislation. First, I have to agree with Senator Levin that it is hard for me to recognize the legislation toward which most of the criticism is directed. It is not the bill that I have read. S. 746 is a fairly balanced bill. It is sensitive to concerns that Americans have concerns with regulation, concerns both that the government do enough to protect us against risk to health and safety and concerns that government not impose undue costs on us, our businesses, our State and local governments.

This is not a bill that overrides concerns for health and safety only to look at economic concerns. It is not a bill that says, look only at quantifiable costs and benefits. It is not a bill that requires agencies to look only at some risks. It seeks to get better information on which to regulate.

Second, given my size, I am very much concerned about anything that is one-size-fits-all. It never fits me. This legislation is not one-size-fits-all legislation. It is generic legislation that deals with all agencies, but it does so in a flexible way. It does so in a way that gives the agencies a great deal of discretion to choose how they will

[1] The prepared statement of Mr. Cass appears in the Appendix on page 100.

comply with the statute. The agencies are given the option of choosing different ways of doing their cost-benefit analysis, different ways of doing valuation, different ways of doing risk assessment, and different ways of doing peer review.

Look, for instance, at the peer review section. It says that agencies can, if they want to, use institutions, panels of experts, or other formal or informal means. If they use a panel of experts, they choose the experts. I do not see any reason to believe the agencies will choose the wrong experts. If you trust the agency, as we said a moment ago, if you trust the agency to do the regulation in the first place, you should trust their choice of experts.

In addition, the legislation has not just one but at least two safety valves in it. There is a safety valve express in the legislation that allows agencies to say, here is why we cannot do this in this case. There are also safety valves in the Administrative Procedure Act whose definition of rules is used in this legislation, so that if there is an emergency, there is not time to go through the ordinary notice and comment proceeding, the agency can choose not to come within the definition of "rule" that is in this legislation.

Third, judicial review. There is an assumption that is made in some testimony that somehow this bill changes what courts are going to do in a radical way and gives courts a tool that they can use to eviscerate health and safety regulation. I do not see that anywhere in this bill. It is a bill that leaves in place the standards of judicial review that exist today. If an agency refuses to comply at all with the law, a court can, but it does not have to, reverse or remand the agency decision.

Other than that, the judicial review provisions intend to, and I think generally do, leave in place the standards of review under the Administrative Procedure Act. In my written statement, I have recommended one small change to make that even more clear.

Thank you again, Mr. Chairman, Members of the Committee, for letting me comment here.

Chairman THOMPSON. Thank you very much. Dr. Crawford.

TESTIMONY OF LESTER M. CRAWFORD,[1] DIRECTOR, CENTER FOR FOOD AND NUTRITION POLICY, GEORGETOWN UNIVERSITY

Mr. CRAWFORD. Thank you very much, Mr. Chairman. I am Director of the Center for Food and Nutrition Policy at Georgetown University, but prior to that assignment, I was in leadership positions in food safety at the Food and Drug Administration and also at the U.S. Department of Agriculture from 1978 to 1991. It is from that perspective that I present my comments on the bill.

I am pleased to note from the last time I testified on a predecessor bill that there has been improvements in the bill that were discussed then, some of which were included in my testimony, and I appreciate that very much, indeed.

I also believe, though, that the new bill is improved in many other ways that I think will help the regulatory process in the Federal Government. I would like to make comment with respect to the food safety and public health aspects of the bill.

[1] The prepared statement of Mr. Crawford appears in the Appendix on page 107.

There are three tools that are institutionalized in the bill. The first is the cost-benefit analysis, and I very much appreciate the earlier discussion among the Senators about this aspect of the bill. One has to be very careful in talking about cost-benefit with respect to human health, death, disease, and suffering, and I appreciate the safeguards that are present in the bill in that regard. Also, I am pleased to see that the bill does not override the so-called super mandate.

The second thing that would be institutionalized—risk assessment—is extraordinarily important and is rapidly becoming the international language of food safety. We recently held a risk assessment consultation at the World Health Organization in Geneva in which an attempt was made to publish, in effect, a book which will recommend to all governments that they use this as the means of communication within the government and also to their various publics and between governments in an effort to make more rational decision making in terms of public health, and particularly food safety.

So I think you are right on the cusp of a revolution in communication both within the government, within the scientific apparatus, and also between regulators and the public and it is going to make a large difference in how we agree on major efforts in public health.

The third thing is peer review, which has been called the surety bond of science. Peer review is the modern day application of the old adage, two heads are better than one. It has been tried in the government a couple of times with great success, in my view.

In 1958, the Food Additives Amendment created the term "generally recognized as safe," which embraces the idea that if you can empanel an uneven number of experts in a field and they say that a substance is generally recognized as safe, then FDA may conclude the substance is safe.

A number of years later, FDA institutionalized while I was there the concept of product specific advisory groups such as the oral contraceptive advisory group, diabetes drug advisory group, and so forth. These are, in effect, peer reviewers who look at the evidence, look at what FDA may be proposing to do, and makes a judgment. The fact that you have included peer review in the bill will make available to the Federal Government in one expertise than has been the case in the past.

I think these three tools would be a great help. Now, let me use the case example to illustrate my point.

Previously, it was mentioned that the Hazard Analysis Critical Control Point system, HACCP, is a new food inspection standard not only in this country but in the world. The United States almost was the leader in this field. We discovered the concept in the United States, and following a National Academy of Sciences study in 1985, we attempted to convert HACCP to a regulatory tool. We were ready by 1989 to propose to the country and also to decision makers at the highest level in this government that the inspection programs be converted to HACCP, but we had difficulty in communicating to OMB the value of the concept because decision making in that distant time, just 10 years ago, was largely intuitive and

subjective and it was difficult for regulators and scientists to find at OMB a common ground for discussion.

We performed risk assessments, but they were not able to take those and see in them the same things we were, so they resorted to various regulatory and administrative subterfuges to slow down the process, one of which and the last of which was the Paperwork Reduction Act. The process envisioned by S. 746 would have averted this unfortunate development. Had we had that, I believe HACCP would have been implemented about 3 years earlier.

I believe that S. 746 will lead to better, more efficient government, and I am convinced the bill provides a framework wherein regulatory initiatives can be fairly and openly judged in a transparent manner. My conclusion is that the bill will institutionalize risk assessment as a calculus for regulatory decision making. To the extent that this is the case, S. 746 will bring the United States in congruence with its international trading partners and the long-sought goal of science-based decision making will at last have been realized.

Thank you, Mr. Chairman.

Chairman THOMPSON. Thank you very much. Dr. Graham.

TESTIMONY OF JOHN D. GRAHAM,[1] PH.D., DIRECTOR, CENTER FOR RISK ANALYSIS, HARVARD SCHOOL OF PUBLIC HEALTH

Mr. GRAHAM. Thank you, Mr. Chairman. I am Professor of Policy and Decision Sciences at the Harvard School of Public Health, where I teach the methods of risk analysis and cost-benefit analysis. Mr. Chairman, I am honored to be here today to offer my enthusiastic support for the Regulatory Improvement Act.

For the last 15 years, I have studied the decision making at Federal agencies responsible for protecting public health, safety, and the environment. Although each of these agencies serve a vital public function, I have found the decisions of these agencies are not always grounded in a good understanding of science, engineering, and economics. As a result, our regulatory system is far less effective and efficient than it could and should be.

One of my previous doctoral students at Harvard, now Professor Tammy Tengs at the University of California at Irvine, found in her doctoral dissertation that life saving investments in the United States are often inefficient. Based on a sample of 200 policies, she estimated that a reallocation of life saving resources to cost-effective programs could save 60,000 more lives per year than we are currently saving at no increased cost to taxpayers or the private sector.

Please let me cite three concrete examples of flawed regulatory decisions that resulted from inadequate regulatory analysis. Example one, the risks of cleaner gasoline, MTBE. In the 1990 Clean Air Act, Congress sought to reduce pollution in city air by ordering EPA to force an increase in the oxygen content of gasoline. EPA later issued a rule that permitted a particular chemical, MTBE, to be used in compliance with the mandate. Now that MTBE is widely used in gasoline throughout the United States, serious questions are being raised about the safety and toxicity of MTBE. There are

[1] The prepared statement of Mr. Graham appears in the Appendix on page 109.

also reports that this highly persistent chemical is contaminating groundwater supplies in several regions of the country.

EPA is now scrambling around trying to find evidence in support of this mandate, and they have recently kicked this issue, this hot potato, to an independent commission. That may be helpful, but what is missing today is the same thing that was missing in 1990, a careful risk-benefit analysis of MTBE and its alternatives.

Example two, mandatory fuel economy standards. During the oil crisis of the mid-1970's, a Federal agency was charged with regulating the average fuel economy of new vehicle fleets. As a result, cars have become more fuel efficient, but they have also become smaller and lighter than they would otherwise have been, causing an additional 2,000 to 3,000 additional traffic fatalities each year because of the inferior occupant crash protection provided by smaller vehicles.

More recently, the objectives of this entire regulation have begun to be circumvented by the growing popularity of sport utility vehicles, a class of vehicles that has not yet been seriously analyzed for its safety and environmental consequences.

Example three, passenger air bags and children. When air bags were mandated in the early 1980's, concerns were raised that the passenger air bag might be dangerous to children seated in the front seat. Technical papers by engineers from General Motors and Honda had already quantified the potential dangers of these air bags to children. The relevant Federal agency, NHTSA, did perform a risk assessment of air bags, but it was not subjected to independent peer review. NHTSA analysts concluded the passenger air bag could endanger children under rare circumstances, but the problem was unlikely to be widespread and serious.

To the agency's credit, now 15 years later, NHTSA has published a real world analysis showing how wrong their early predictions were—increases of 20 to 100 percent in the risks to children in cars with passenger air bags have been shown. In this case, NHTSA designed a regulation that has harmed children unnecessarily because the underlying analysis was flawed and never subjected to independent peer review.

Looking back on these three examples, it must be acknowledged that we have much more knowledge today than Congress and agencies had when these regulations were originally formulated. The benefits of hindsight are certainly considerable. Nonetheless, it is my opinion that in each of these cases, the regulatory decisions and the subsequent actions by Congress might have been very different and smarter if the agency had performed the kinds of analysis mandated in the bill we are discussing today.

Thank you very much, and I look forward to the question period.

Chairman THOMPSON. Thank you very much. Ms. Kenworthy.

TESTIMONY OF PATRICIA G. KENWORTHY,[1] VICE PRESIDENT, GOVERNMENT AFFAIRS, NATIONAL ENVIRONMENTAL TRUST

Ms. KENWORTHY. Good morning, Mr. Chairman. On behalf of the National Environmental Trust, I wish to thank you and Senator Lieberman, as well as other Members of this Committee, for the op-

[1] The prepared statement of Ms. Kenworthy appears in the Appendix on page 118.

portunity to present our views today about S. 746. I am Vice President for Government Affairs and Senior Attorney at the National Environmental Trust, and prior to joining NET 2 years ago, I was Director of Regulatory Affairs for Monsanto Company.

We believe there are a number of serious problems with the bill. It will, in our opinion, greatly increase the time required for agencies to make regulatory decisions. No provision is made for a corresponding increase in resources to address these newly imposed burdens. We believe that attempting to accomplish sweeping reform by enacting a single comprehensive statute is bound to result in unforseen and unintended consequences, including in some cases subjecting new rules to inappropriate analysis that was never intended by the authorizing statutes.

Senator Lieberman mentioned the Toxic Release Inventory law. I would like to take that example a little bit further, although quite a bit has already been said about it here this morning.

As has been discussed, this law is not a risk-based statute. It is simply a community right-to-know law. It is an example of the potential for unintended consequences that this legislation would create. By the way, our information is that TRI rules have been subjected to the Executive Order and under that test would certainly be subject to the mandates of S. 746.

If TRI laws and other community right-to-know laws and many other examples that can be enumerated of rules to which this statute would create unintended consequences, we believe simply that those things should be specifically excluded. As Senator Lieberman pointed out in his response to the Chairman's comments, we can all read the statute a different way about the applicability of some of these things. It is not all that clear.

We read S. 746 to require that a risk assessment be performed before a new regulation can be promulgated in order for the benefits to be calculated. This brings up an important point about risk assessment and cost-benefit analysis generally. These evaluations are not a panacea to prevent bad regulatory decisions. Risk assessment and cost-benefit evaluations inform, surely, but do not provide answers to hard questions. The answers to how to regulate a particular risk must in the end always be based on value judgments.

We have heard a great many anecdotes and examples here this morning intended to demonstrate how irrational the existing system is and that are supposed to show that S. 746 would improve the system. In any large and complex regulatory system, there will be errors, there will be foolish results, and there will be bad decisions. As Senator Durbin has pointed out, in some of the particular cases we have heard about this morning, there has been and is more to the story.

In any event, S. 746 would not have changed the outcome of most of the examples we have heard this morning, even if it had been enacted. The better approach, in our opinion, is to deal with particular situations, with particular problems that may arise from individual statutes on a case-by-case basis.

There is very real potential for unintended consequences when an attempt is made to reform perceived regulatory problems with a comprehensive piece of legislation. This bill attempts to address

an array of many different statutes that have diverse purposes and goals. These many affected statutes are administered by many different Federal agencies with distinct missions. We do not think this kind of comprehensive legislation can possibly effect improvement under those circumstances. We believe that, instead, it would create confusion and inconsistencies and do great harm to agencies' abilities to protect health, safety, and the environment. It is for these reasons that we oppose this legislation.

Thank you again for this opportunity to testify.

Chairman THOMPSON. Thank you very much. Dr. Mirer.

TESTIMONY OF FRANKLIN E. MIRER,[1] DIRECTOR, HEALTH AND SAFETY DEPARTMENT, INTERNATIONAL UNION, UNITED AUTOMOBILE, AEROSPACE, AND AGRICULTURAL IMPLEMENT WORKERS OF AMERICA (UAW)

Mr. MIRER. Thank you very much, Mr. Chairman. I am very pleased to be back. Senator Levin, I bring greetings from Green Acres.

Chairman THOMPSON. We are having a reunion of a lot of old friends today, are we not?

Mr. MIRER. Right.

Senator LEVIN. Old neighbors.

Mr. MIRER. I heard a lot of John Graham's issues when I was on his advisory board and I am pleased to speak again. In part of my role in the UAW, I visited 46 foundries myself. Dealing with the previous example, spent foundry sand is filled with carcinogens. The workers that breathe that dust suffer excess mortality from lung cancer. The exposures are only partly regulated by OSHA, partly as a result of 13 years of litigation by the UAW. We would hope to address the rest of them. So I would not view foundry sand as safer than dirt myself and would not have it in my backyard.

Next week, the UAW will observe Worker Memorial Day. Hundreds of local unions will fly flags at half mast to recognize workers killed, injured, made ill on the job. Many of the fatalities and virtually all of the occupational disease identified among our members by research arose from conditions not covered, or exposures permitted by existing OSHA standards. We are back here opposing S. 746 because it contains no provisions that would facilitate improving OSHA standards, and would do the opposite.

In my testimony, I describe the history of metal working fluid standards, as yet another example of the real world potential of S. 746. There are about a million American workers exposed to metal working fluids. Our efforts began in the early 1980's when we did several studies in Connecticut bearing plants showing increased cancer among our members there.

My full testimony describes an outbreak of serious lung disease, hypersensitivity pneumonitis at Chrysler's Kenosha engine plant, affecting dozens of workers, some of whom will never come back to work. I talk about the extraordinary efforts of Chrysler, UAW Local 72, the Wisconsin Health Department, and NIOSH in responding to this problem.

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[1] The prepared statement of Mr. Mirer appears in the Appendix on page 132.

The key point is that there was no exposure in that facility remotely approaching OSHA's permissible exposure limit, and no OSHA requirement for medical surveillance for those employees that would have stemmed the outbreak before it got as bad as it did.

We have been working on this problem a while, starting in the 1980's. After a decade of research, we petitioned OSHA for a new standard. In 1993, after 4 years, OSHA formed a 17-member standards advisory committee. We have had eight or nine meetings, traveled around the country. After we get done, there will be at least a 2-year delay to get the proposal issued with the existing processes, even to get to a public hearing. That is the present situation.

Now, if S. 746 were to become law, even if the 17 members, union, management, and public health representatives reached complete agreement on every issue in the standard, OSHA would still have to conduct a new formal risk assessment, a different cost-benefit analysis than what is required under the statute, a substitution risk analysis, comparative risk analysis. Then OSHA would have to subject it to peer review before the proposal would be formally issued for public comment. So the specific provisions in this bill would add years of additional delay.

I also want to talk a little bit about the so-called peer review provisions. From personal experience as a peer reviewer, they are actually substantially less accountable, less transparent, less open than the current OSHA procedures. OSHA now holds an informal public hearing on the proposal to which everybody can come, everybody can ask questions, and all the evidence is questioned by the parties of interest. The process is open, on the record, exhaustive. The President's Commission on Risk Assessment and Risk Management recognized this as equivalent to peer review.

By contrast, the additional peer review process required in S. 746 is closed. Participation is limited. By its nature, workers would be excluded from participation and it would involve industry representatives with conflicts of interest and it permits decisions to be made on secret information.

I have done peer review of journal articles and peer review of grants. Peer review is a secret, closed process. Sometimes, the identity of the reviewer is concealed from the person who submitted the journal article, and the identity of the author of the journal article is concealed from the reviewer. So I just do not think it is an appropriate process, certainly not in all cases, and not as good as what we have now.

I make some other general points about whether the specifications in the bill and cost-benefit analysis are appropriate, whether it is burdensome or not. The bill kicks in with an OSHA standard that costs the average employer $17 a year. A major rule at OSHA is something that costs an employer $17 a year.

Let me close by saying what would really solve some of the regulatory problems, the standard setting problems at OSHA and see whether we see any of these in S. 746.

First, I think it is important to recognize that the OSHA process is actually more transparent, open, and accountable than the new peer review process and that has to be specified.

Second, we have got a lot of off-the-record, opaque, hidden processes in this business already, SBREFA review, some of the aspects of OMB review not fully covered by the Executive Order or the language here. All of that has to be brought into the open so that we, the advocates of the regulation, have the right to question those people who are involved in the regulatory process.

Third, we have to provide the same access to judicial remedies for the parties who wish to challenge the agency's failure to act. As much of the litigation at OSHA is over agency's failure to act to protect, as those who would oppose action.

And finally, not only will this legislation add delay to the standards process that is already decades long, but it will also reduce the number of hazards which the agency can take up by soaking up resources for some analyses that are irrelevant.

So I think those four issues have to be addressed if we are going to have anything like a balanced approach to public health protection. Thank you very much.

Chairman THOMPSON. Thank you very much. Mr. Vladeck.

TESTIMONY OF DAVID C. VLADECK,[1] DIRECTOR, PUBLIC CITIZEN LITIGATION GROUP

Mr. VLADECK. Thank you, Mr. Chairman, Members of the Committee. Thank you for inviting me again to testify on this bill.

I bring to the table 20 years of experience as a lawyer representing consumers, workers, and others who are dependent on our health and safety agencies to protect them from hazardous workplaces, from foods that may be adulterated, from dangerous drugs and other consumer products. It is difficult for me to find myself in disagreement with people who I respect and people who share common aspirational goals.

We all want to see better, more efficient, and improved rulemaking and decision making. But today, our health and safety agencies are on the brink of paralysis. OSHA takes 10 years or more from start to finish to get a rule out to protect workers. That is intolerable. It can take EPA just as long. The Department of Agriculture, as Dr. Crawford already made clear, spent years developing HACCP. It is not in place today and there is no HACCP standard for prepared or packaged meats that is even on the table.

I would suggest to Congress that it ought to tackle the gridlock that now paralyzes our regulatory agencies rather than look at S. 746, which will only add to that delay.

I would like to start out this morning by talking about how and why S. 746 is going to condemn agencies to regulatory paralysis. One thing that S. 746 does that has not been talked about is it dictates a structure that agencies must follow in their rulemaking process. This is clear. This is not flexibility by any stretch. The first thing that the agency must do, well before it begins formal rulemaking, is it has to publish notice that it is about to undertake a risk assessment. It must solicit information from the regulated industry as well as from the public. That is before it begins.

It is also required to consider all relevant information that is reasonably available. This requirement is unbounded. It is not limited

[1] The prepared statement of Mr. Vladeck appears in the Appendix on page 143.

durationally. It extends until the date the final rule is published. It is an undoable task for the agency to be on a treadmill, always assimilating new data when it comes in, yet that is a requirement of this bill.

The agency then has to follow what I believe are relatively prescriptive requirements for risk assessment, requirements that are far more prescriptive than exist today in the Executive Order or any other source of law.

Finally, the agency then has to submit its risk assessment to a peer review organization. That will take time. This is just the first step of the agency's sequence, because the agency is directed to include the results of the risk assessment in the cost-benefit analysis, which is the second step of this sequence. This, too, is a laborious, long process that will require the agency to devote considerable time and effort to preparing before it even begins the rulemaking.

Then, again, a new requirement, unmatched anywhere else in law, agencies must address substitution risks, and for agencies like OSHA and EPA, which by definition regulate where there will be substitution risks, this, too, is a very considerable task.

Only after the agency completes all of these tasks may it take even the first step in the regulatory process, which is to publish a notice of proposed rulemaking. It cannot be seriously argued that this bill will not add considerably to the delay that is already paralyzing our regulatory agencies. That is wrong. It is bad policy.

The second thing I would like to talk about is judicial review. I disagree with my good friend, Ron Cass, that the judicial review provision in this bill is benign. I think there are many problems with it. I would like to focus only on one.

It has at least been commonly understood in discussions with staff that this bill was not intended to allow a rule to be set aside or remanded if the agency performed the risk assessment, performed a cost-benefit analysis, but did not do so in the manner prescribed by the statute. I do not think this bill, the way it is drafted, achieves that result, and there are three reasons for my conclusion.

The first is, this bill does not contain language that was in its predecessors that said rules could be remanded only if the agency failed entirely to perform these functions. That language has been deleted.

Next, the bill says that the adequacy of compliance with specific requirements of this subchapter shall not be grounds for invalidating the rule. But the phrase "adequacy of compliance" suggests that compliance with specific requirements is reviewable, but adequacy is not. It is a dangerous formulation that invites mischievous judicial review.

And third, and this is my last point, the act sets forth very prescriptive provisions governing risk assessment, cost-benefit analysis, and so forth. A reviewing court is going to be skeptical that you in Congress wanted the agency to do this but could simply put in a piece of paper labeled "risk assessment" and that would foreclose judicial review. I think that is an untenable position to take. I think the way this provision is drafted, you are inviting courts to set aside agency rules simply because the agency, in performing the risk assessment, the cost-benefit analysis, did not dot its "i"s

and cross its "t"s. That could have devastating consequences for agency rules.

Chairman THOMPSON. Thank you very much.

On your last point first, Senator Levin and I have spent a long time on this, and if somebody can come up with a way to make this clearer, I would welcome the suggestion. The idea that the court can throw the analysis out because of the adequacy of the cost-benefit analysis or the risk assessment is just totally unfounded. I do not know how it could be any clearer.

It says in Section 627(d), the cost-benefit analysis, cost-benefit determination under Section 623(d) and any risk assessment required under this subchapter shall not be subject to judicial review separate from review of the final review to which such analysis or assessment applies. The cost-benefit analysis, cost-benefit determination under Section 623(d) and any risk assessment shall be part of the rulemaking record and shall be considered by a court to the extent relevant only in determining under the statute granting the rulemaking authority whether the final rule is arbitrary and capricious and abuse of discretion or unsupported by substantial evidence where the standard is otherwise provided by law. Then Section 623(e) says that if you fail to perform the cost-benefit analysis or risk assessment, a court may remand or invalidate the rule.

Can you think of a way that we can draft that to make it any clearer? Obviously, the rule in and of itself, if it is arbitrary and capricious, the court can throw it out, but the court clearly cannot pick out the cost-benefit analysis or the risk assessment and consider that individually and the adequacy of that individually in order to throw the rule out. It goes into the entire rule and the court has to consider the rule. Can it be any clearer than that?

Mr. VLADECK. Well, I take it your question is directed to me. I think it could be much clearer and I think you should go back to the language in the Glenn-Chafee bill that included a qualifier between fails to perform such as entirely and you take out the lead in the next sentence, the adequacy of, because what you are doing is you are inviting the court to review—not to review adequacy, but to do a checklist.

Remember, under this statute, a cost-benefit analysis is only one done in accordance with the strictures laid out in the statute. If you look at Section 621, the definition of cost-benefit analysis says it is one performed in accordance with the mandates laid out later on in the statute. If you take out that language, you significantly alleviate the possibility that a court will do what I have just said, which is——

Chairman THOMPSON. Take out what language, the adequacy of?

Mr. VLADECK. The adequacy of.

Chairman THOMPSON. And just say the compliance?

Mr. VLADECK. The first thing I would do is I would go back to Glenn-Chafee. That is the best and clearest way to fix this concern, which is to use a qualifying phrase like—and I would be glad to work with your staff on this, and Paul knows these arguments backwards and forwards—but to use qualifying language like that, that would make it crystal clear to a reviewing court that if, for example, the agency failed to—in the risk assessment requirement,

you have to describe the major uncertainties in each component of the risk assessment. If you have failed to do that, that may be grounds——

Chairman THOMPSON. But it says that the risk assessment shall not be subject to judicial review, separate and apart.

Mr. VLADECK. No, but suppose there is a challenge to an agency final rule? One argument that will be made is that the final rule is not rational. It is arbitrary and capricious because there are flaws in the risk assessment. The flaw in the risk assessment——

Chairman THOMPSON. And that would be valid only if it is so flawed that it makes the final rule arbitrary and capricious.

Mr. VLADECK. I am suggesting another ground for remand.

Chairman THOMPSON. I beg your pardon?

Mr. VLADECK. I am suggesting a different ground for remand. The argument you made is the conventional argument. Yes, the rule itself is irrational as demonstrated by the flaw in the risk assessment. There is a second line of argument made available under this bill, which is that the risk assessment is flawed because it omits consideration of something mandated by this rule. Therefore, the agency failed to perform the risk assessment as Congress has decreed and that independently may provide a reviewing court a ground for setting aside or remanding a rule.

Chairman THOMPSON. We cannot give risk assessment total immunity. I mean, no matter how flawed it is, it becomes a part of the rule. You have to look at the rule including the risk assessment.

Mr. VLADECK. Risk assessments are already judicially reviewable. In fact, courts look at them all the time. The UAW—in a case that I represented them—won an OSHA case challenging the adequacy of a risk assessment. There is nothing unusual or unconventional about that.

Chairman THOMPSON. This has some additional elements that the court considers.

Mr. VLADECK. That is correct.

Chairman THOMPSON. Professor Cass, what am I overlooking here? We tried to provide a belt and suspenders to this thing and still, evidently, we have not accounted for the imagination of good lawyers. What do you think?

Mr. CASS. Well, Mr. Vladeck is right about one thing, and that is that he and I disagree on this. [Laughter.]

I think the legislation is crystal clear on this point. I think you cannot read Sections 622 and 627(d) and (e) and come to the conclusion that a court is invited to go off and do a detailed review of the risk assessment and then throw it out if the judge does not like the way it has been done.

Unfortunately, in my profession as a law professor, we tend to focus on the really odd case, on the court that goes way off the deep end. There are 22 million civil actions a year of which the Supreme Court hears argument in about 85, and one of those every few years makes it into a case book. Those are the ones we spend all our time on. It gives us something of a warped view of the system.

I think this legislation is quite clear. I do not see the risk that Mr. Vladeck does here at all.

Chairman THOMPSON. All right. Let me ask some of you to address another criticism that we have heard fairly consistently. The reference is made to the OSHA process and perhaps the EPA process, it takes 10 years to get a rule, and so forth. I assume going in there is an awful lot that we all agree on here that we are trying to do, and transparency is good, using the best scientific analysis is good. Even having some, regardless of what kind of review it is, having some process or someone of expertise, if it is fair and balanced, looking at all of this. A lot of this is incorporated in the Executive Order. So, as I say, we pay lip service that this is a good idea. If it is not a good idea, it should not be in the Executive Order.

But having agreed on all those things, there still is clearly concern that what we are doing here is going to slow down the process. It takes, let us say, 10 years to get some of these rules done. There is one major OSHA rule a year or something like that, I guess.

Dr. Graham, what would be your feeling about that?

Mr. GRAHAM. Mr. Chairman, I wanted to share with the Committee the results of a book provocatively entitled "The Fifth Branch: Science Advisors as Policy Makers," written by Professor Sheila Jasanoff, then at Cornell University, now at the Kennedy School of Government. And what she did is she reviewed those health, safety, and environmental agencies that currently use independent peer review. She looked at case studies of what happens when independent experts from universities and think tanks review the analyses performed by agencies.

Let me give you just a paraphrased summary of her conclusions. One scientific peer review can actually shorten the rulemaking process by increasing technical consensus about whether regulation is necessary and increasing the credibility of the agency in the decisions that it makes.

Two, when scientific peer review is routine and rigorous, judges are less likely to second guess agency decisions because those decisions have been supported by independent scientific peer review.

Third, it is a myth that scientific peer review is a pretext for delaying decisions. Early peer review can actually accelerate regulatory decisions by building consensus about what science says on the issue.

Four, agencies have developed workable procedures for handling conflict of interest issues, though continued vigilance is required.

The academic literature on this subject, the studies of the actual peer review process, do not suggest that some of the perilous stories that you have been told would actually take place.

Chairman THOMPSON. Are there any examples of where a cost-benefit analysis was used in order to expedite a process or make a process more politically palatable, to allow it to take place sooner, in your opinion?

Mr. GRAHAM. I do not know an example on the cost-benefit analysis off the top of my head, but I think there is a very good one in the case of the Safe Drinking Water Act. Under the Safe Drinking Water Act, there already is a mandatory requirement for independent peer review. In the case of nitrates, a contaminant of drinking water, an agency scientist misread the underlying toxicological and epidemiological literature and was going to set a

standard that was not protective enough of infants who might be exposed to nitrates. The independent peer review process exposed this error and caused the agency to set the maximum contaminant level tighter than it otherwise would have been. That is a case of peer review making the process more protective of public health and the environment. So I do not think we should assume that peer review is going to be a bad thing for these public health agencies.

Chairman THOMPSON. Before my light goes off, let me ask Dr. Crawford. I will get in under the wire here.

Mr. CRAWFORD. Yes. I agree with Dr. Graham. I guess every witness has more or less said that some of these rules take too long. We have talked about some that took 10 years. I can tell you one when I was at FDA that took 24 years.

But the question is whether or not we are going to do something about it or whether we are just going to continue to bemoan the fact that the regulatory process is out of control. I think these systems, as Professor Graham mentioned, when I was in the government, would have helped us establish diplomatic relations with OMB and we could perhaps, I believe, have gotten things like HACCP through much quicker. I just know we could, because we eventually had lost communications and also perhaps scientific credibility that peer review and risk assessment would have given us back.

Chairman THOMPSON. Thank you very much. Senator Levin.

Senator LEVIN. Thank you, Mr. Chairman.

Mr. Vladeck has testified that the USDA could not have initiated, and these are his words, the HACCP rule, or at best would have been severely hampered by it, had S. 746 been in effect, and I am wondering, Dr. Crawford, whether you agree with that.

Mr. CRAWFORD. Actually, in the predecessor bill hearing last year, we did evaluate HACCP under what would happen if the bill had been passed. We found out that HACCP would have passed with flying colors. There would be a $2 billion, as I recall, on the plus side for HACCP. So that, again, would have been a compelling case for us to override OMB's worries about the Paperwork Reduction Act, whatever that was.

Senator LEVIN. Would it have gone through possibly even faster?

Mr. CRAWFORD. It would have gone through, I would say, 3 years faster.

Senator LEVIN. If this bill were in effect?

Mr. CRAWFORD. Yes.

Senator LEVIN. Now, if there is a case where these provisions are creating delay, and I will ask you, Mr. Vladeck, is it not true there is a provision in this bill which says that the agency may proceed without taking these actions if doing so, if conducting the regulatory analysis, would be contrary to an important public interest? You at least agree that language, that safeguard is in the bill?

Mr. VLADECK. Yes, sir.

Senator LEVIN. I know you do not think it is adequate, but you would agree, at least, the language is there?

Mr. VLADECK. You have my position.

Senator LEVIN. All right. Now, you have also testified, Mr. Vladeck, that S. 746 requires that an agency "certify that its rule

optimizes economic efficiency," and then you go on from there. I would suggest to you that you are going back. We do not have a certification the way Glenn-Chafee did. Glenn-Chafee, a bill which many of the groups supported, now oppose our bill. Glenn-Chafee had a requirement that there be a certification that the rule produce benefits that will justify the costs.

Indeed, the Executive Order which we now have says that each agency shall assess both the cost and the benefits of the intended regulation, and recognizing that some costs and benefits are difficult to quantify, propose or adopt the regulation only upon a reasoned determination that the benefits of the intended regulation justify the costs. That is the current Executive Order.

We do not do that. We do not have a requirement that there be a determination that benefits justify cost. We do not have a certification. We have a determination as to whether or not the rule is likely to provide benefits that justify the costs, and then if it does not, why it is that the agency proposes to regulate.

So in your testimony, you are using a word which appeared in Glenn-Chafee which is a much more restrictive word on the agency than what we have here, and I would just simply urge you as we proceed with discussion of this bill that we focus on the language of this bill. And this bill, again, has a determination as to whether a rule is likely to provide benefits that justify costs and this bill says, if not, then why is the agency proposing to regulate. It is a much more flexible standard for the agency than the current Executive Order and it is more flexible than Glenn-Chafee in this particular regard. Feel free to comment on that, if you wish.

Mr. MIRER. Senator Levin, could I comment on that?

Senator LEVIN. Yes.

Mr. VLADECK. I think my statement, when read in context, is accurate. Your bill says the agency must make a determination whether the net benefits test is met, and what my focus is is not on the word "certify" or "determine," it is on "net." Every dictionary you look at suggests that you are talking about a mathematical quantification.

Senator LEVIN. Even though it says quantifiable or non-quantifiable?

Mr. VLADECK. Yes, because the word "net" is the modifier. There has never been any explanation of why that is not an incoherent standard, to say to the agency, on one hand, you must use this mathematical net benefits test. On the other hand, you can use non-quantifiable factors.

Mr. MIRER. At the risk of being practical here——

Senator LEVIN. Well, the only——

Mr. MIRER. If I could just say, in the OSHA process——

Senator LEVIN. I am just going to have to comment on this, and I have got a time limit, so forgive me. The bill itself says, and I want to read the language here, on page 14, line 14, I want to read the language. "Net benefit analysis shall not be construed to be limited to quantifiable effects."

Mr. VLADECK. As I acknowledged.

Senator LEVIN. I just want to simply read the language, without arguing it with you.

Mr. MIRER. Now, here is the practical point. In the OSHA process, and I do not know how anybody does this at any other agency, in the OSHA process, there is no credible economic information available until we get to the hearing. All the feasibility information, the cost of control, the options that could be taken, the substitutions of chemicals that might take into account, none of that stuff comes out until the hearing. When it gets to the hearing, OSHA does a preliminary analysis, which is usually very weak and limited, partly because of the Paperwork Reduction Act, and then in the hearing, workers who actually do the jobs and employers who actually run these processes come forward with the real data and it is possible to make the determination.

So what this process is doing is requiring all that to be done prior to getting to the hearing, holding up the hearing until it can be done, peer reviewing it before we can get to the hearing to get to the real data, and then I guess the agency has to, if there is substantial new evidence that comes out at the hearing, which is the purpose of having the hearing in the first place, they would have to go through the process again.

So that is our argument for why this front loading, which is destructive anyway, of the process as we see it is not a good idea.

And then the second point is that this cost-benefit, etc., is not the economic feasibility standard, to which OSHA is held and so it is irrelevant, and as Senator Levin said, information can lead to a result, even if it does not mandate the result. That is exactly what we are afraid of here, overriding the underlying protections in the OSHA statute, even if it is not the intended result.

Senator LEVIN. This question, Dr. Graham, is for you, as to whether or not the peer review which is provided for in this bill is duplicative of what the rulemaking process already provides in the area that they discussed.

Mr. GRAHAM. I think that the literature that exists on peer review shows that certain agencies, such as FDA and parts of EPA, currently use peer review processes, and I think those would satisfy the requirements of this bill. Other parts of EPA, other parts of FDA and OSHA, do not currently have an independent peer review process. In those cases, they would be asked to institute what is already being done at other programs.

But I think there is a lot of flexibility in the way the peer review provision is written that would allow different agencies to tailor the kind of peer review that is appropriate for the kinds of rules they are developing.

Senator LEVIN. So the bottom line is, then, that the requirements on peer review do not duplicate——

Mr. GRAHAM. They would not have to do it twice. I see nothing in there that suggests to me they would have to do it twice or three times.

Senator LEVIN. I think that is all I have for this round. Thank you.

Chairman THOMPSON. Thank you very much. Senator Voinovich.

Senator VOINOVICH. I listened to Dr. Mirer's testimony and Mr. Vladeck's. I am a new member of the Senate and what I am hearing today is that we have agencies out there that are already taking a long time to move things through them. I am also hearing

that if we require them to do more, it is going to take a longer period of time.

I wear hearing aids today because when I was a construction laborer, there was not a requirement that you have the ear plugs. I have an uncle that died prematurely, I think, because he worked with chemicals and he got leukemia.

Mr. Chairman, I just wonder, do we have a problem with some of these Federal agencies in terms of the adequacy of the number of people that work in them? It is like we do not have enough people to get the job done, and if that is the problem, then why do we want to load them up with some more stuff? The object is to try and have regulations that are sensible and make sense and protect people and do what they are supposed to be doing.

If the problem is that we do not have the wherewithal in these departments, then I think that this Committee ought to be very, very much concerned about that. I am thinking maybe you ought to bring in those agencies and talk to them about how adequate are they in terms of the staffing that they need to get the job done that they are supposed to be doing. It is fundamental.

As a governor, I had great complaints, for example, about our medical board in Ohio, that they were not doing the job that they were to be doing, so we got involved in it and doubled the money that was made available to them and put new people on the board. I think 2 years ago or last year, it is the best medical board now in the country in terms of getting rid of these people that should not be practicing medicine.

So I think that maybe there is another problem here that we need to address our attention to, in addition to just looking at this legislation.

One of the criticisms that we heard, that if you have cost-benefit analysis and risk assessment, it is going to end up in a situation where you are going to put dollars over the values of the lives and health of our citizens. You hear it all the time, and I would like any panelist that would like to, to comment on that.

Mr. CASS. I would be happy to, Senator. I think that there is no doubt that all of us every day make choices where we are trading off some type of risk against some type of cost. There is no other way to live. We do not have unlimited resources and we live in a world where those choices are necessary.

If we look at the amount of money the Federal Government has, even at its current level, it is limited, and the amount of money we have in the economy is limited. The agencies have to be saying at some point, is the amount of dislocation, cost, imposition on others worth this saving in health and safety? It has got to be implicit in what they do now.

What this legislation says is not to make a precise, quantifiable point at which you value human life. What it says is not pin down the unique solution to this problem. It says to look carefully at how much different types of rules are going to cost and see if you can do what you want more cost effectively—see if you can prevent more risk more cheaply. And I think that is a good instruction to give agencies.

Mr. MIRER. I do not think that there is any question that agencies try to do that now. The heightening of the importance of regu-

latory analysis is actually the bottleneck at OSHA. The system is being run by the people who do the economic analysis, and the leader of that group was just put in charge of all standard setting. So instead of the health scientists or the engineers being the critical skill, the critical skill is being able to get out these analyses that will withstand Executive Order review, that will withstand the subsequent challenges in court and the like, and that is the dominant feature. That is what is slowing things down.

When we come to the question of cost-benefit, one of the first standards that OSHA took up was the noise standard, and that would be, by any measure, a major rule. The problem is what is the value of a worker's hearing? That would actually be the thing over which we struggled. Those ear plugs that you were provided with, we now know they do not work anywhere near as well as they were supposed to work, and people are losing their hearing even if they religiously wear those hearing protection devices.

So now we are getting to balance the cost of quieting the noise, and it is doable, against human hearing and what is the value of a worker's hearing. I actually do not know how to put a number on that, but I can tell you that putting that as a cost-benefit question has stopped progress on noise abatement in American industry now. We have not had any progress in 10 or 15 years as a result of that cost-benefit determination being made, actually by a review commission judge, not even by a real court.

Senator VOINOVICH. Do any other panelists want to comment here?

[No response.]

Senator VOINOVICH. I am finished.

Chairman THOMPSON. You have a little time left, so I am going to take 30 seconds of it.

Senator VOINOVICH. I yield my time to the Chairman.

Chairman THOMPSON. You are right. I mean, the difficulty you point out is a correct one. But the other question is, what is the best rule in order to prevent loss of hearing? And you also said in your statement, we know more about ear plugs now than we did then. So I think your point is well taken, but it is only a part of the picture. We are talking about not only the value of it but what is the best way to protect whatever value that a person might put on it in view of current science, in view of what we know now, and work all that into the process to come out with the best results, right, Senator Durbin?

Senator DURBIN. Right. Thanks, Mr. Chairman.

Is there anyone on the panel who believes that the passage of this legislation will not add to the responsibility of the agencies covered? Is there anyone who believes that the agencies will need fewer employees because we pass this bill, as opposed to their current employee workload?

Mr. CASS. I do not believe that you will need fewer employees, but I do not believe that for agencies, generally, you will be making any significant addition to the burden on them. Most of the agencies you are addressing these requirements to have very similar requirements at present, and generally, when things are slow at an agency, the answer is politics, not science, not administrative practice.

Senator DURBIN. Mr. Vladeck.

Mr. VLADECK. I would like to respond to that. There are huge differences between this bill and the Executive Order that add all sorts of analytic burdens to the agency that they cannot possibly meet with existing staff. You can just tick them off quickly.

The Executive Order does not have a peer review requirement. The Executive Order does not prescribe across-the-board risk assessment. The Executive Order does not prescribe the net benefits test. The Executive Order does not change judicial review. The Executive Order does not require the consideration of substitution risks.

So there are a lot of differences—plus, the Executive Order does not require anything amounting to the detail that is required in this statute for cost-benefit analysis and so forth. So there should be no pretense. There is no way agencies can do this with their existing staff.

Senator DURBIN. I agree with Mr. Vladeck on this point. I wanted to let everyone have a chance to say what they thought about it, and when I offered an amendment before this Committee last year which said, do not go forward with this if the agencies certify you are going to in any way hamper their core mission, for example, the Environmental Protection Agency and the inspection standard and so forth, I lost 10 to 5. It appears we want to do this on the cheap, and I think Senator Voinovich has made my point. We would like to impose new mandates on these agencies in terms of what they are going to do, the list that Mr. Vladeck said, and not provide them the resources.

Let me ask Dr. Graham, I know a little bit about oxygenated fuels because I come from ethanol land. As I understand your testimony and my memory of what was involved in it, in an effort to reduce air pollution, we suggested the use of oxygenated fuels——

Mr. GRAHAM. Mandated it.

Senator DURBIN [continuing]. Mandated oxygenated fuels, but permitted them to use ethanol or MTBE. The permission was given. It was not a mandate that they use it in a certain area.

Mr. GRAHAM. EPA did a rulemaking in which they could have compared the risks and benefits of alternative oxygenated fuels. They could have provided technical information that would have caused people to go to one oxygenated fuel or another. They did not do so. They just let politics and market forces play it out and——

Senator DURBIN. They let the private sector play it out?

Mr. GRAHAM. Right. And the public health and the environment oftentimes need EPA to exercise scientific and public health leadership, which did not happen.

Senator DURBIN. I think you are calling for more regulation, and it is——

Mr. GRAHAM. Senator Durbin, I am an advocate of public health, safety, and environmental regulation——

Senator DURBIN. So am I.

Mr. GRAHAM [continuing]. Smart regulation based on science.

Senator DURBIN. My point is that many of us thought MTBE was dangerous to start with, for a lot of the reasons that have now been discovered, but the marketplace was allowed to work it out, if you will, and then——

Mr. GRAHAM. And it might have been different if, in fact, EPA had done an authoritative comparative risk assessment of MTBE versus the alternatives.

Senator DURBIN. Let me ask about this. Everybody keeps using the phrase independent peer review. Let us test how independent peer review is under this bill. Should peer review be limited to both industry and government experts who have no financial interest in the outcome of the decision? Does anybody disagree with that? If you have a financial interest in the outcome of the decision, should you be sitting on a peer review panel under this bill?

Mr. GRAHAM. You should not let industrial scientists numerically dominate the peer review panel. I think that it would be a big mistake, but Senator Durbin, to say in the case of a peer review of an air bag design issue that you are going to exclude all of the air bag supplier engineers, all the air bag manufacturer engineers, you are just going to exclude them from the peer review. That would be a big mistake and loss of critical expertise.

Senator DURBIN. Well, let me suggest here, this bill, if I read it correctly, excludes those in government agencies from serving on the peer review panels——

Mr. GRAHAM. I do not read it that way. Those particular government employees involved in developing the regulation, but other aspects of the agency or the Federal Government, I read this as saying that they could potentially serve on it.

Senator DURBIN. One of the objections made by OMB last year, by Mr. Raines, was, for example, in the area of nuclear regulatory activity, there are a limited number of government experts here, and when we start excluding certain agencies from participating, then we exclude resources that may not be easy to duplicate.

Mr. GRAHAM. Right.

Senator DURBIN. But I find it interesting that you use the word "dominate". I do not know how you can predict in advance who is going to dominate a peer review. Is someone going to be milquetoast meek or stand up and say, "I am in charge here. I am the jury foreman."

Mr. GRAHAM. Right, but industry scientists should not numerically dominate.

Senator DURBIN. That is a little hard to call, and if you are saying that if we are going to do an air bag peer review, we certainly ought to bring in somebody from General Motors and Ford to sit there, is this then an independent peer review?

Mr. GRAHAM. I think it would be very hard to construct a technically competent peer review on air bag design issues and have no engineers from the air bag supplier community and from the manufacturing community.

Furthermore, if you look at the history of peer review at Federal agencies, which is what this book does, what you find is that in most cases, the dominance in the peer review in terms of the number of participants, they are either from academic organizations or from nonprofit research institutions. There would on occasion be one or two members from a regulated community or from a labor union or from a public interest group. But the dominant involvement in these peer review panels in terms of number of participants and overall influence on the process are people who do not

have any particular stake in the outcome, and that is the way it should be.

Mr. MIRER. If I could——

Senator DURBIN. I am sorry.

Mr. MIRER. I have been on a lot of peer review groups myself, at the National Academy of Sciences, National Toxicology Program, Board of Scientific Counselors, which peer reviews the report on carcinogens and the like. My trouble with the peer review requirement, certainly in the OSHA context, is that, yes, you want people who have an interest in the outcome to be involved in the rulemaking process, who have the expertise. I agree with Mr. Graham on that.

What I do not agree with is saying that these people get special crack at the rule before anybody else gets it. That is the problem with the process as it is set up in the bill now, the detriment of the process relative to OSHA.

Peer review groups involve—there is another conflict of interest which is not talked about. The academic reviewers are often reviewing their own work and evaluating the quality of their own work and how dispositive it is of the rule. That is a grievous conflict, actually, and may even be the dominant one on these committees. Stuff is decided based on extra-record evidence, and prejudices of the individuals—free ideas, and frankly, they are not bound by criteria in legislate or regulation.

I mean, you take a full professor of oncology on one of these committees. He does not necessarily believe he has to follow the rules. He thinks he is better than the rules, so he is not following them, and that is just the way it is. It is an inherent problem with the methodology and I think we have this in the system now.

Senator DURBIN. We have lionized and sanctified peer review in this panel, and after some of the comments here, I am a little bit suspicious as to the product we can expect to come from it.

But let us go a step further. Should we have public access to the peer review? Should people be able to judge for themselves who dominated, whether the right people were chosen?

Ms. KENWORTHY. Senator Durbin, could I speak to that? I have had some experience during my working career with FIFRA, the insecticide law, pesticide law, scientific advisory panel as well as with the EPA Science Advisory Board. Both of those processes work routinely with public scrutiny. They announce their meetings in the *Federal Register* ahead of time and people are allowed to sit in. Oftentimes, the public is permitted to be present when the regulated entity presents its side of the issue.

Those processes generally have worked extremely well. I think, particularly if you are going to have peer reviewers who are financially dependent upon the regulated entity, that is all the more reason for the need for public scrutiny.

Senator DURBIN. Thank you. Mr. Vladeck.

Mr. VLADECK. Yes. It bears mention that this bill reverses the presumption that normally attaches to peer review activity. Most peer review committees are governed by the Federal Advisory Committee Act, which mandates very broad openness, not simply with respect to the meetings but with the working papers and so forth of the Committee. There is nothing in this bill that mirrors that.

In fact, it is explicitly made not applicable, which means that there may be even internal papers generated by the peer review committee that would not be made public. That is a serious problem.

Senator DURBIN. Yes. Dr. Crawford.

Mr. CRAWFORD. I have a couple of experiences which might be worthwhile. As you know, the National Academy of Sciences last year asked itself to be excluded from the Federal Advisory Committee Act because they believed certain aspects impeded scientific decision-making. Congress granted that request.

Then another point is that when FDA approves drugs, food additives, and so forth, this is not an open process. They may hold hearings or public advisory committee meetings but the final decision is reserved to FDA staff.

Another way is that some of the FDA committees, like the Food Advisory Committee, requires members with vested interests to be non-voting members. That would be a third way of dealing with the perceived problem.

Senator DURBIN. Thank you. Thank you, Mr. Chairman.

Chairman THOMPSON. Thank you very much. Senator Edwards.

OPENING STATEMENT OF SENATOR EDWARDS

Senator EDWARDS. Thank you, Mr. Chairman. I decided when I was sitting in my office and Senator Durbin started to talk about tobacco, I had better get down here. [Laughter.]

Senator DURBIN. I am leaving.

Senator EDWARDS. Let me say first that I have enjoyed the discussion. This subject, I think, is a fascinating subject. I think the bill intends to do some very positive things. I do not think there is any question about that.

It seems to me we ought to be trying to improve efficiencies, reduce bureaucracy. I am personally concerned about the human impact of this bill, if it were to pass. I just wonder whether, ultimately, this bill, which I think has a very laudable goal, accomplishes what it is we are trying to accomplish, which is to, for example, to improve agency efficiency, to get these OSHA regulations, EPA regulations, passed more quickly, whether we are reducing unnecessary regulatory bureaucratic burdens that are placed on businesses, and I emphasize unnecessary.

A lot of the arguments that have been made on both sides of this bill lead me to the conclusion that it is still a bill that I am open minded about, but I have real concerns about it, very serious concerns.

Let me just ask you sort of a generic question to start with and whoever wants to respond. Does anyone believe that this piece of legislation, in fact, makes agency rulemaking more efficient? And tell me why.

Mr. CRAWFORD. Yes, I do, because at the present time the first thing that happens is the agency decides to announce that they have an intention to regulate by publishing an advance notice of proposed rulemaking, and the way an agency comes to that point may vary from a petition that is sent in, it might be a letter from a citizen of the United States or someone who is not even a citizen and it is not routinized. There is no decision making matrix that they have to conform.

So, consequently, petitions that turn into regulations can lay in abeyance for 4 or 5 years before they come up with some sort of structure to put them together. This would give them that structure and it would make it routine throughout the Federal Government, and over time, through experience, I believe S. 746 would make the whole process more efficient and certainly more transparent. It would be more like what goes on in other countries and groups of countries, like the European Union, where risk assessment has become the order of the day and the state of the art.

Ms. KENWORTHY. Senator Edwards, could I respond to that, just briefly?

Senator EDWARDS. Yes, of course.

Ms. KENWORTHY. First of all, I do not agree that because you have put all of those additional requirements, front load the process with all of those additional requirements, that we are improving efficiency here. What we are doing is putting more and more steps and more and more process into the whole system.

But further to that, I have to say, businesses should be efficient. That is how they succeed. Sometimes governments should be efficient, but not always. There are other things that governments need to do besides focusing on efficiencies, and indeed, if that were the only focus of the government, we would lose a lot of our democratic protections.

Senator EDWARDS. I agree with that, Ms. Kenworthy.

Mr. MIRER. No, I do not think it is more efficient. Dr. Crawford actually mentioned one of the defects, I think, in the current approach, that it is unbalanced because there is not anything in there which pushes the agency to respond to a petition and to justify equally the failure to act. Right now, agencies have to defend against pretty strong attack when they act. There is no similar pressure on the agency to defend a refusal to act and to put protections forward. If there were something like that in the bill, you could consider it at least a balanced attempt, but there is nothing like that in the bill.

Senator EDWARDS. Yes. Mr. Vladeck.

Mr. VLADECK. Let me just add one thought. You have to look at this bill in the context that exists in a regulatory environment that, particularly in the last few years, has layered requirement upon requirement for agencies to overcome in order to regulate. You have SBREFA, you have the Congressional Accountability Act, you have a host of new enactments, and that no one has stood back and simply assessed their impact on the agency.

If the question is, does this add to the agency's efficiency, you have to ask, where are the agencies today? And if you look at the literature on administrative law, it is quite clear that agencies have suffered from a process of ossification. They are now so process-laden because of requirements imposed by Congress, the Executive Order, the courts, they are like the giant who is simply tied down with all this rope.

All this bill does is add some more rope. It does not add to the agencies' efficiency. It certainly does not add to the informational mix that is out there today. If you look at the agency rulemaking record, there is tons of information about cost, about risks.

So if your question is, does this optimize efficiency, the answer has to be no.

Mr. GRAHAM. Senator Edwards, if we asked an engineer at North Carolina State or at Duke or something like that to serve on a peer review panel for an EPA regulation, from the perspective of the agency analyst, that may look a little frightening and it may look a little like it is a layer of hoop they are going to have to go through because this person is going to comment on their work and potentially slow the process down.

But I think the point of this book by Sheila Jasanoff is when the regulation is actually done and after the dialogue between the experts and the agency officials, the ultimate product is actually a smarter regulation, one that is more protective and less costly than it would have been without that review.

So I am not sure if that is efficient or not efficient, but I think it potentially is a step in the right direction.

Senator EDWARDS. I want to ask about a couple of specific things in the proposed bill, starting with peer review. Do any of you have any notion of how many rulemaking procedures or what percentage of rulemaking procedures actually meet this threshold criteria for peer review, which appears to me to be affecting the economy by $500 million or more for health and safety?

Mr. MIRER. Anything that costs the average employer $87 a year will meet that requirement.

Mr. CASS. The only estimate I have seen, Senator, is that there are roughly two dozen rules that would meet a $100 million threshold.

Senator EDWARDS. Those were two very different answers.

Mr. GRAHAM. Yes, they were very different statements.

Senator EDWARDS. Let us start with you, Professor Cass, if you could tell me the basis for that conclusion.

Mr. CASS. In testimony offered last year by Professor Ernie Gellhorn, he had gone through the rules and looked at the number that met the $100 million threshold and his estimate for that was about 25 rules annually.

Senator EDWARDS. And out of how many rulemakings that occur each year?

Mr. CASS. There are thousands that occur every year, and there are thousands of pages added to the *Federal Register* every year by these agencies that are so bound down that they cannot pass regulations.

Senator EDWARDS. Well, if you are correct, the bottom line is there would be very few peer reviews that would actually occur.

Mr. CASS. I believe so.

Senator EDWARDS. I see everybody at that end of the table shaking their head yes and I see everybody at this end shaking their head no, so can I get a response?

Mr. MIRER. We are back to—we had this colloquy last year. Mr. Thompson said, "See, there were no OSHA regulations that were affected by this," and I said, "Yes, that is the whole point. There are no OSHA regulations——"

Chairman THOMPSON. You see, I did not ask you that this year.

Mr. MIRER. No, you did not ask that question again, but you did. The situation is OSHA regulates 6.5 million employers. Anything

with broad impact is going to be a major rule. The example I always use is lighting an exit sign, which I did last year, too, and I heard the sigh. Actually we do not have a lit exit sign here like we ought to have, but Congress is exempt from OSHA, or maybe not exempt anymore. But if you light that exit sign with a 50-watt bulb, you are over $17 a year. So that is an example of the reach that this bill would have. An information statute, an information rule affecting large numbers of employers would get caught up in this, and basically anything with broad application.

Now, I am not opposed to economic analysis of these rules because I think the economic analysis drives stricter regulation than you would get if you had just a bunch of people sitting around a table wondering about what things would cost. My only concern is that we have to get to the hearing quicker when we have real economic data because you do not have that in advance of the hearing, which is when it would be peer reviewed.

Mr. GRAHAM. Senator, I would repeat the threshold is $500 million, actually, on the cost-benefit peer review.

Senator EDWARDS. I know it is, and I think that is what I said.

Mr. GRAHAM. That is a big threshold.

Mr. MIRER. That is $85 a year.

Mr. GRAHAM. I would encourage you to ask CBO if you are not sure about this. I think you will find out it is a limited number of regulations.

Senator EDWARDS. I wanted to ask you a couple other specific questions, but let me just say, I did not mean to indicate that I think efficiency takes precedence over human life and environmental concerns. I absolutely believe the opposite of that.

Mr. GRAHAM. You did not say that.

Senator EDWARDS. But I do think we want to make these agencies as efficient as they can.

You said something, Dr. Graham, that I just want to make sure I understood, and I do not want to take much time on it because I have something else I want to ask.

Mr. GRAHAM. All right.

Senator EDWARDS. I heard you saying in response to Senator Durbin's question—he expressed a concern that I also share, which is it appears to me that industry representatives who have a financial interest in or could have a financial interest in the outcome of any particular rulemaking procedure can clearly participate in the peer review process.

Do I hear you saying that you believe that is justified, even though obviously we give up some objectivity and independence by having them on the panel?

Mr. GRAHAM. Yes.

Senator EDWARDS. Do you believe that is justified because they bring information and expertise to the discussion? Is that basically what you are saying?

Mr. GRAHAM. Right, and the standard conflict of interest procedures at the National Academy of Sciences and at the EPA Science Advisory Board would call for disclosure, public disclosure of that conflict and they would never allow more than a couple of those participants for fear of dominating the peer review panel. But there are many cases where the necessary expertise on the subject mat-

ter in question would require an engineer, a scientist, or an economist from one of the affected regulated parties, and I think that is perfectly appropriate.

Senator EDWARDS. Mr. Vladeck, if I could have just another second, Mr. Chairman, could I get you to respond to that, please?

Mr. VLADECK. Our concern—I mean, I think there is a legitimate argument for having people with an interested stake to debate the issues. There is ample opportunity today for anyone who is interested in an agency risk assessment or cost-benefit analysis to share their views with the agency. That is the whole point of notice and comment rulemaking.

What is wrong about this bill is it gives people with an interested stake in the outcome a privileged place in the rulemaking proceeding denied to every other member of the public. They will have access to information other people will not have. They will have the ability to demand written responses from the agency and they will get their crack at the rulemaking process well before there is even a notice of proposed rulemaking published.

Senator EDWARDS. Basically, what I hear you saying is they can provide their expertise, counsel, etc., without being on the peer review panel?

Mr. VLADECK. Absolutely, and they do so in every major rulemaking today.

Senator EDWARDS. Thank you all very much.

Chairman THOMPSON. But the agency, of course, as it is now, can control pretty much what it agrees to hear and how it agrees to hear it.

On peer review, just so that we all understand what this bill requires, it says that panels must be broadly representative, expertise relevant to the sciences, etc., and who are independent of the agency, independent of the agency involved, not of the government in total. You can bring governmental experts in. Then be governed by agency standards and practices governing conflicts of interest and non-governmental agency advisors.

So for people concerned about conflicts of interest, we are using the current agency rules on conflicts of interest now. So if it is a conflict of interest before this law, it will be a conflict of interest after and vice-versa.

Then in terms of flexibility, it says the formality of the peer review conducted under this section shall be commensurate with the significance in complexity of the subject matter. It says that a member of an agency advisory board shall be considered independent of the agency, so you are not excluding agency advisory boards. I guess we are always wanting people who know the most about it but have no interest in it.

Mr. GRAHAM. There are not many people. The Martians are not going to do peer review.

Chairman THOMPSON. It is an inherent impossibility. But I go back to something Senator Edwards and I know a little something about, is that it is not that you can always find a witness that has absolutely no interest in it, it is that you disclose it. Then, one way or another, that is factored into the credibility of the information that you are getting. So I do not see any other way to do it.

I appreciate this panel today. Senator, I appreciate your commitment to keep an open mind on this for a while. [Laughter.]

It seems to me what we are trying to do here, we are all trying to reach a good result, and I agree with you that efficiency is not the main goal of this particular act. We deal with efficiency a lot on this Committee. We have a high risk list where we have agencies year in and year out who are on a list that have a real problem with waste, fraud, and abuse, and they come in year after year after year, high levels of waste, fraud, and abuse in the agencies, and I seldom, if ever, hear them say, "We just do not have enough people to deal with it." There are all different kinds of excuses.

What we are trying to do in a democratic society, I think, is try to come up with a system so that no one is unaccountable. That is part of the problem we have with the Independent Counsel Act now. We cannot set someone or a group of people up and say, you are not accountable. We do not want to do anything to slow you down, even though we know you are going in the wrong direction sometimes, and creating bad rules and rules that hurt people sometimes.

So it has to do with accountability and transparency and requiring them to give reasons for what they are doing, and then at the end of all that, we do not say you have to do anything about it except give you reasons for what you are doing. Then if you are so far off the mark, some Federal judge will look at all of it and tell you so, not in terms of micromanaging what you did but looking at the rule as a whole. If it is arbitrary and capricious, and you know how high that standard is, then a Federal judge might get involved. As Jonathan Swift would have said, "I think it is a very modest proposal."

We have had a good hearing today. You have all been excellent witnesses, as usual. We appreciate your time very much and we look forward to working with any and all of you as we go forward to see if we cannot do everything we can to come together as much as might be possible. So thank you very much.

I would like to include in the record a statement from Ed Wasserman, President of the American Chemical Society, regarding S. 746.[1]

With that, we will adjourn.

[Whereupon, at 12:49 p.m., the Committee was adjourned.]

[1] The letter from Mr. Wasserman dated April 14, 1999, with an enclosed prepared statement appears in the Appendix on page 154.

APPENDIX

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

THE DIRECTOR

STATEMENT OF
JACOB J. LEW
DIRECTOR
OFFICE OF MANAGEMENT AND BUDGET
FOR THE
COMMITTEE ON GOVERNMENTAL AFFAIRS
UNITED STATES SENATE

April 21, 1999

Mr. Chairman and members of this Committee. I appreciate the opportunity to submit a statement concerning S. 746, the "Regulatory Improvement Act of 1999." This bill was introduced on March 25, and reflects a long history of arduous efforts by many Members of this Committee.

This Administration has been both an advocate and implementor of responsible regulatory reform. The President has signed into law a number of important pieces of reform legislation, and the Administration is taking a wide range of administrative steps to improve the regulatory process. For example, under the guidance of Executive Order No. 12866, agencies are developing flexible performance standards and using market incentives whenever possible; are applying benefit-cost analysis to achieve objectives in the most cost-effective manner; and are reaching out to the affected parties, particularly our State and local partners, to understand better the intended and unintended consequences of a proposed regulatory action. Under Executive branch direction, agencies are improving delivery of services, reducing red tape, and reforming practices to focus on customer service. The Administration's goal in taking these actions is to streamline and reduce the burden of government on its citizens, improve services, and restore the basic trust of public in its government.

As you know, the Administration believes that regulatory reforms tailored to the specifics

of particular statutes and agencies are preferable to across-the-board regulatory reform legislation. Recent examples include the Safe Drinking Water Act amendments, the Food and Drug Administration Modernization Act, and the Food Quality Protection Act. Nonetheless, we stated our views, and offered certain suggestions concerning the broader approach addressed in S. 981 which was considered in the Committee last year. You took our concerns seriously, and S. 746 includes the changes we suggested at that time. On July 15, 1998, I sent Senator Levin and Chairman Thompson the attached letter, summarizing some of this history and our views and concerns. Our views today remain the same as stated in that letter. If S. 746 emerges from the Senate and House as you now propose, the President would sign it.

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

July 15,1998

THE DIRECTOR

The Honorable Carl Levin
Committee on Governmental Affairs
United States Senate
Washington, D.C. 20510

Dear Senator Levin:

Thank you for your letter of July 1, 1998, in which you respond to the views on S. 981 that we expressed in former OMB Director Frank Raines' letter of March 6, 1998.

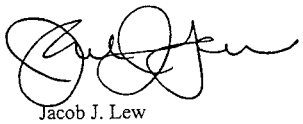
President Clinton has been a strong supporter of responsible regulatory reform. In addition to signing into law a number of important pieces of reform legislation, he and Vice President Gore are taking a wide range of administrative steps to improve the regulatory process. For example, under the guidance of Executive Order 12866, agencies are developing flexible performance standards and using market incentives whenever possible; are applying benefit-cost analysis to achieve objectives in the most cost-effective manner; and are reaching out to the affected parties, particularly our State and local partners, to understand better the intended and unintended consequences of a proposed regulatory action. Under the leadership of the Vice President's National Partnership for Reinventing Government, agencies are improving delivery of services, reducing red tape, and reforming practices to focus on customer service. The Administration's goal in these actions is to streamline and reduce the burden of government on its citizens, improve services, and restore the basic trust of public in its government.

The debate on comprehensive regulatory reform legislation is one that has sparked great passion and has provoked, as you aptly note in your letter, "distrust and friction among the interested parties." We heartily agree with you that, to say the least, "[t]he path to this point has not been easy." In part, this has been the result of earlier versions of this legislation proposed by others that sought not to improve the nation's regulatory system, but to burden and undermine it. In a variety of ways these bills would have created obstacles and hurdles to the government's ability to function effectively and to protect the health, safety, and environment of its citizens. In particular, these bills would have created a supermandate, undoing the many protections for our citizens that are carefully crafted into specific statutes. In addition, strict judicial review and complex analytic, risk assessment, peer review, and lookback provisions would have hampered rather than helped the government's ability to make reasonable decisions and would have opened the door to new rounds of endless litigation.

We appreciate your thoughtful efforts over the past year to respond to issues that we and others have raised. In your latest letter you continue to take seriously our concerns. Indeed, the changes you indicate that you are willing to make would resolve our concerns, and if the bill emerges from the Senate and House as you now propose, with no changes, the President would find it acceptable and sign it.

I should note, however, that our experience with past efforts to resolve these differences suggests that good ideas and the resolution of differences can be destroyed during the long process of getting a bill to the President's desk, and the nuances and balance that we have all sought in this legislation could be easily disrupted. Many of the terms used carry great meaning, and further modification is likely to renew the concerns that have animated our past opposition to bills of this type. Accordingly, we look forward to working with you to ensure that any bill the Congress passes on this subject is fully consistent with the one on which we have reached agreement.

Sincerely,



Jacob J. Lew
Acting Director

Identical letter sent to the Honorable Fred Thompson

Congress of the United States
House of Representatives
Washington, DC 20515

July 31, 1998

The Honorable Jack Lew
Director
Office of Management and Budget
Old Executive Office Building
17th Street and Pennsylvania Ave., N.W.
Washington, D.C. 20503

Dear Mr. Lew:

As Minority Leader, Minority Whip, and Ranking Members of Committees of the House of Representatives with jurisdiction over statutes designed to protect public health, safety, and the environment, we are writing with respect to S. 981, the "Regulatory Improvement Act of 1998." In light of prior so-called "regulatory reform" proposals which would have undermined those statutes, we remain concerned that a one-size-fits-all approach, which makes changes across a wide range of agencies and statutes, may have serious, and perhaps unintended, adverse consequences.

We have only recently been informed of your July 15, 1998, letter to Senators Levin and Thompson and wish to gain a fuller understanding of the changes that S. 981, if enacted, would make to our environment, health, and safety laws.

We appreciate your cooperation in providing timely responses to our initial questions which are attached.

Sincerely,

Richard A. Gephardt
Minority Leader

David E. Bonior
Minority Whip

John D. Dingell
Ranking Minority Member
Committee on Commerce

George E. Brown, Jr.
Ranking Minority Member
Commitee on Science

Henry A. Waxman
Ranking Minority Member
Committee on Government Reform
and Oversight

William Clay
Ranking Minority Member
Committee on Education and
the Workforce

John Conyers
Ranking Minority Member
Committee on the Judiciary

James L. Oberstar
Ranking Minority Member
Committee on Transportation and
Infrastructure

George Miller
Ranking Minority Member
Committee on Resources

QUESTIONS

(Unless otherwise noted, references are to S. 981 as agreed to in the Lew letter dated July 15, 1998)

General

1. During the process of consultation leading to the agreement on S. 981 contained in Director Lew's July 15th, 1998, letter, please indicate whether and to what extent any of the following agencies were consulted, whether such agencies approved the text as agreed to, and whether such agencies prepared any written comments relating to the proposed or final agreement: the Environmental Protection Agency, the Food and Drug Administration, the Consumer Products Safety Commission, the Federal Trade Commission, the Federal Mine Safety and Health Review Commission, the Nuclear Regulatory Commission, the Federal Aviation Administration, the Occupational Safety and Health Administration, the National Highway Traffic Safety Administration, the Office of Science and Technology Policy, the Agency for Toxic Substances and Disease Registry, the National Institute of Environmental Health Sciences, the National Institute for Occupational Safety and Health, or any other federal agency with regulatory or scientific responsibilities relating to the environment, public health, or safety. Please provide copies of such written materials.

2. Section 621(10)(J) substantially expands the scope of rules exempted from the Act's requirements from prior versions.

a) What, if any, agency actions and rules under the Federal Insecticide, Fungicide, and Rodenticide Act would be exempted by this provision?

b) Would this provision exempt agency rules and actions, including drug and medical device approvals, under the Federal Food Drug and Cosmetic Act?

c) Would this provision exempt agency rules and actions under the Food Quality Protection Act?

d) What other agency rules and actions would be exempted under this provision?

e) What is the rationale for exempting these specific examples of agency rules and actions? Why are these specific regulations or acts set out for special treatment?

3. After considering the exemptions provided for in Section 621, please identify each specific statute that would be subject to the requirements of S. 981.

4. To further assist us in understanding the scope and reach of S. 981, please identify:

a) each rule issued or agency action taken since August 1, 1995, to which the requirements of S. 981 would have applied, and

b) each rule or agency action that the Administration believes, based on current information and projections, is anticipated to be issued within the next three years that will likely trigger or be subject to the requirements of S. 981.

5. Please provide, in consultation with the agencies that administer the statutes, a detailed side-by-side comparison of the risk assessment, cost-benefit and peer review requirements of S. 981 with any risk assessment, cost-benefit and peer review

requirements contained in current environmental, health, and safety statutes that would be covered by S. 981. To the extent that such requirements are inconsistent or conflicting, which statute would govern?

6. Based on actual agency experience, please provide cost and time estimates (both low and high end) for (a) risk assessment, (b) cost-benefit analysis, and (c) peer review for major rules that would be subject to the requirements of S. 981.

7. Please identify the differences between Executive Order 12866 and S. 981, including differences in their scope and application, their specific requirements for cost-benefit analysis, risk assessment, and peer review, and their enforceability through judicial review. In particular, does Executive Order 12866 require an agency head to make a determination whether a rule is "likely to achieve the rule making objective in a more cost-effective manner, or with greater net benefits, than the other reasonable alternatives considered by the agency" as required by section 623(d)?

Regulatory Analysis / Cost-Benefit Analysis

8. Less than two years ago, Congress passed and the President signed into law the Safe Drinking Water Act Amendments of 1996, which carefully evaluated how costs and benefits were to be considered in promulgating regulations for the Safe Drinking Water Act. While the Safe Drinking Water Act requires the Administrator to publish a determination as to whether the benefits of a maximum contaminant level "justify or do not justify the costs," it does not require a "greater net benefits" test such as that imposed by section 623(d)(1)(B). Has the EPA analyzed the impact of this "greater net benefits" requirement? If so, please provide a copy of any such analysis. Even it becomes only a preference, could it create a bias against regulations that provide substantial non-quantifiable benefits?

Risk Assessment Requirements

9. What is the relationship between the elements in the definition of the term "risk assessment" in section 621(9) and the elements of a risk assessment required in section 624(e)? The definition (section 621(9)) seems to require a characterization of a distribution of risk and other elements "to the extent feasible," while the mandated elements of a risk assessment in section 624(e) are required "to the extent scientifically appropriate." Are these intended to be the same standard? If a risk assessment does not have all of the elements listed in the definition in 621(9), is it exempt from the statute?

10. Section 624 requires agencies to design and conduct a risk assessment for "each proposed and final major rule the primary purpose of which is to address health, safety, or environmental risk." Section 627(b) states that a determination by an agency that a rule is or is not a "major" rule can be set aside by a reviewing court if it finds the determination to be arbitrary or capricious. What about the determination that the "primary" purpose of a rule is to address health, safety, or environmental risk? Who would make such a decision, and would it similarly be subject to interlocutory appeal or other judicial review? Why is a decision by an agency whether a rule is "major" for the purposes of the Act subject to judicial review, while the same decision by the OMB Director is not subject to judicial review?

11. In Director Raines' letter of March 6, 1998, the Administration objected to provisions in S. 981 which applied to risk assessments which were not the basis of a major rule. However, S. 981 requires that risk assessment principles apply to non-rulemaking risk assessments which the Director "reasonably anticipates is likely to have an annual effect

on the economy of $100 million or more in reasonably quantifiable costs and that the Director determines shall be subject to the requirements of this section." Please state the reasons for the position taken by Director Raines in March, 1998.

a) Since such an assessment by itself imposes no legal restrictions or other obligations, how would the costs of such a risk assessment be "reasonably quantified"? What would such costs include?

b) What process will be required to ensure that the Director is informed of all non-rulemaking risk assessments in order for the Director to determine in advance of such risk assessment whether or not the statutory risk assessment principles should apply?

12. Section 624(c)(2) requires "scientific assumptions used in risk assessments" to "incorporate all reasonably available, relevant, and reliable scientific information." (Emphasis added.)

a) How does this requirement differ from the requirement in 624(b) which requires each agency to consider in each risk assessment "all relevant, reliable, and reasonably available scientific information"?

b) How are "scientific assumptions" defined? Since all assumptions in a risk assessment are based on some type of scientific information, does this mean that all assumptions in a risk assessment are subject to these provisions?

c) Assumptions are usually used in a risk assessment when there are two or more equally plausible scientific alternatives to be chosen in the absence of direct data. Doesn't having to choose one alternative over another inherently preclude the agency from incorporating "all" relevant scientific information in that assumption?

d) The choice of alternative rests on policy considerations or other non-scientific information. How can such policy considerations be considered to incorporate "all" relevant scientific information?

13. S. 981 requires a risk assessment to be conducted and peer reviewed before an agency can publish a notice of proposed rulemaking. Given the amount of time it takes to promulgate a major rule, there will certainly be new scientific information available by the time the rulemaking is completed. Despite section 624(a)(2) and section 625(h), an agency would risk having a rule overturned if it failed to conduct another risk assessment and peer review in order to meet the requirement of section 624(b) that agencies consider "all reasonably available, relevant, and reliable scientific information" in conducting a risk assessment. How would the bill prevent the situation where a risk assessment is being perpetually revised because new information is always becoming available?

14. Section 624(d) requires an agency to solicit and consider "relevant and reliable data" from the public in conducting a risk assessment. Who decides whether the data provided by the public is "relevant" and "reliable"? By what criteria?

15. In March, Director Raines objected to the bill's requirement that risk assessments be conducted for rules which are not "premised on the outcome of a risk assessment," for example, rules that require the use of "best available control technology." What was the basis for the Administration's objection? Is it the Administration's position that S. 981 should require risk assessments to be conducted for non-risk-based statutes? If so:

a) How many additional annual risk requirements will be required for rules which are not premised on the outcome of a risk assessment? What will such legally irrelevant risk assessments cost the agencies in terms of funding and delays in regulation?

b) What is the rationale for an agency to conduct a risk assessment meeting the strict statutory requirements of S. 981 if such a risk assessment is irrelevant to the statutory criteria for making a regulatory decision?

c) Based on EPA's experience conducting risk assessments under section 112 of the Clean Air Act prior to the 1990 Clean Air Act amendments, how much will it cost and how long will it take for EPA to carry out risk assessments for determinations under section 112 even though such assessments are no longer legally relevant to the regulatory decision?

16. Section 627(d) provides for judicial review of risk assessments only as part of the judicial review of a "final rule to which such ... assessment applies." Would a risk assessment which is not the basis of a rulemaking proceeding be considered "final agency action" under section 627(a)(1)? Or does mean that a risk assessment which is not the basis of a rulemaking cannot be judicially reviewed under any circumstances? How would this provision, if enacted, affect the decision in Flue-Cured Tobacco Cooperative Stabilization Corp. et al v. EPA (U.S.D.C. N.C., July 17, 1998)?

Peer Review

17. In March, Director Raines objected to the bill's requirement that agencies conduct independent peer reviews for cost-benefit analysis. S. 981, however, requires peer reviews for major rules with an effect of $500 million in "reasonably quantifiable costs." What was the basis for Director Raines' position in March?

18. In March, Director Raines objected to the bill's provision (section 625(b)(ii)) which prohibited any agency employee from participating on a peer-review panel, and recommended instead that only program office employees should be barred from a peer review panel. S. 981, however, still bars any agency employee from participating in the peer review even if such employee had no connection with the rulemaking proceeding.

a) What was the basis for Director Raines' objections in March, 1998?

b) Which agencies presently prohibit all agency employees from sitting on peer review advisory panels? Is that consistent with the present policy of EPA, as indicated in the "Peer Review Handbook" published in January 1998 by EPA's Science Policy Council?

19. Section 625(b) (1)(B) permits each agency to set its own rules regarding conflicts of interest by peer review panelists. Under this provision, could agencies permit persons with direct financial conflicts of interest to serve on peer review panels? Why does S. 981 permit agencies to have different standards for conflicts of interest when it requires them to have uniform standards for cost-benefit analysis and risk assessment?

20. Section 625(b)(1)(c) states the principle that peer review should be conducted in time to meet agency deadlines. However, since the peer review panel is independent of the agency, how does an agency ensure that the mandatory peer review process is completed in time to meet statutory or court-ordered deadlines? Does an agency have the authority

to ignore a peer review panel if it does not meet agency-set deadlines? What happens if the peer review panel feels it cannot credibly conduct the peer review in the time period provided?

21. What is the basis for exempting the peer review panels from the requirements of the Federal Advisory Committee Act (5 U.S.C. App)? Would this provision permit the peer review panel to conduct meetings closed to the public?

22. In his March 1998 letter, Director Raines sought to delete the reference to "peer review" from the judicial review requirements of section 627(e). What were the reasons for the Administration's policy position set forth in Director Raines' letter?

Comparative Risk Analysis

23. Section 628(c)(2) requires the Director of OIRA, in consolation with the Director of OSTP, to contract with an "accredited scientific institution" to develop comparative risk and other risk-related methodologies. In March, 1998, the Administration objected to this language. What was the basis for the Administration's objection in March?

24. Please identify the scientific institutions that have the expertise to conduct such a broad study. On what basis would the accredited scientific institution be chosen? What safeguards will be instituted to avoid conflicts of interest? What risks are considered to be "significant" risks? Are the risks to be compared limited to risks that are within the statutory authority of federal regulatory agencies to regulate, or would they include all possible health, safety, or environmental risks? Where will the scientific institution obtain information to evaluate such a broad range of risks and how will data gaps and scientific uncertainties be accounted for? What is the anticipated cost of the study and why do you believe two years is the appropriate amount of time?

25. Section 629 requires a comparative risk study to be carried out by "an accredited scientific institution." Section 629(c) requires agencies within 4 years after the effective date of the Act to use the results of the study as appropriate in the preparation of the agency's budget and strategic plan and performance plan under the Government Performance and Results Act. Would such a requirement override the statutory and budgetary priorities established by Congress? Do you agree that the priorities and requirements set forth in the agencies' authorizing statutes should take precedence for the purpose of budgets, strategic plans, and performance plans?

26. The report accompanying the bill acknowledges that comparative risk analysis is not "purely a scientific undertaking" because "public values must also be incorporated when assessing the relative seriousness of the risks and when setting priorities." (Committee Report at 49) According to the Committee Report, the comparative risk analysis required by section 629 should enable "public values to be ascertained and considered."

a) Why is "an accredited scientific institution" competent to "ascertain and consider" public values for the purposes of ranking risks and setting priorities? How will such an institution determine whether the public thinks that cancer prevention is more important than preventing birth defects?

b) How can such value-laden priority-setting exercises be subjected to peer review as required by S. 981?

Executive Oversight

27. Section 643 has been weakened to require disclosure only of written "correspondence" (rather than "communications") and of matters discussed only in "significant meetings" (rather than "substantive" meetings) between OIRA and outside parties. Given the bill's intention to make rulemaking decisions more transparent, what is the rationale for limiting the disclosure of contacts between OIRA and outside parties relating to an agency rulemaking? In particular, why has the Administration agreed to a provision which requires less public disclosure than its own Executive Order 12866, which requires OIRA to maintain a publicly available log of "all substantive oral communications, including meetings and telephone conversations"?

28. There is a well-documented history, particularly in prior Administrations, of OMB delays in clearing agency rules. Executive Order 12866, issued by President Clinton, provides for a 90 day OMB review period of covered regulations which may be extended for an additional one-time 30-day period upon written approval of the Director and at the request of the agency head. In contrast, the bill allows OIRA to unilaterally extend the review period for agency rules longer than 90 days without any time limit and without the approval of the agency head. Why has the Administration agreed to override the language of its own Executive Order?

29. To what extent, if any, would the statutory authority of the OMB Director to extend the review process take precedence over the statutory deadlines established by Congress for many environmental, safety and health rulemakings? Would the deadline established by Congress in the underlying statutes provide an outside limit for the OMB Director's review authority? Could such a statutory deadline be enforced by court action even if such a rule were delayed by OIRA review under this section?

30. Under Executive Order 12866, OIRA is required to provide a written explanation to an agency to which it has returned a regulatory action for further consideration. S. 981 has no similar provision. Would the Administration support adding such a provision to S. 981?

United States General Accounting Office

GAO

Testimony

Before the Committee on Governmental Affairs
U.S. Senate

Not to be Released
Before 10:00 a.m. EDT
Wednesday
April 21, 1999

REGULATORY REFORM

Comments on S. 746--The Regulatory Improvement Act of 1999

Statement for the Record of L. Nye Stevens
Director, Federal Management and Workforce Issues
General Government Division

GAO/T-GGD/RCED-99-163

Statement

Regulatory Reform: Comments on S. 746—The Regulatory Improvement Act of 1999

Mr. Chairman and Members of the Committee:

I am pleased to assist in your consideration of S. 746, the "Regulatory Improvement Act of 1999." As I said in my testimony on its predecessor, S. 981, we believe that the bill thoughtfully addresses many issues in regulatory management that have long been the subject of controversy.[1] We have issued reports on a number of those issues.

My statement today focuses on our past work in four areas of relevance to the bill: (1) the effectiveness of previous regulatory reform initiatives, (2) agencies' cost-benefit analysis practices and the trigger for the analytical requirements, (3) peer review of agencies' regulatory analyses, and (4) the transparency of the regulatory development and review process.

Unfunded Mandates Reform Act Had Little Effect on Agencies' Rulemaking Actions

During this Committee's hearings on S. 981, one of the witnesses indicated that Congress should determine the effectiveness of previously enacted regulatory reforms before enacting additional reforms. Perhaps the most directly relevant of those reforms to S. 746 is title II of the Unfunded Mandates Reform Act of 1995 (UMRA), which requires that agencies take a number of analytical and procedural steps during the rulemaking process.

We examined the implementation of UMRA during its first 2 years of operation and, for several reasons, concluded that it had little effect on agencies' rulemaking actions.[2] First, the act's cost-benefit requirement did not apply to many of the rulemaking actions that were considered "economically significant"actions under Executive Order 12866 (78 out of 110 issued in the 2-year period). Second, UMRA gave agencies discretion not to take certain actions if they determined that those actions were duplicative or unfeasible. For example, subsection 202(a)(3) of the act requires agencies to estimate future compliance costs and any disproportionate budgetary effects of the actions "if and to the extent that the agency determines that accurate estimates are reasonably feasible." Third, UMRA requires agencies to take actions that they were already required to take. For example, the act required agencies to conduct cost-benefit analyses for all covered rules, but Executive Order 12866 required such analyses for more than a year before UMRA was enacted and for a broader set of rules than UMRA covered.

[1]Regulatory Reform: Comments on S. 981—The Regulatory Improvement Act of 1997 (GAO/T-GGD/RCED-97-250, Sept. 12, 1997); and Regulatory Reform: Comments on S. 981—The Regulatory Improvement Act of 1998 (GAO/T-GGD/RCED-98-95, Feb. 24, 1998).

[2]Unfunded Mandates: Reform Act Has Had Little Effect on Agencies' Rulemaking Actions (GAO/GGD-98-30, Feb. 4, 1998).

Like UMRA, S. 746 contains some of the same requirements contained in Executive Order 12866 and in previous legislation. However, the requirements in the bill are also different from existing requirements in many respects. For example, S. 746 would address a number of topics that are not addressed by either UMRA or the executive order, including risk assessments and peer review. These requirements could have the effect of improving the quality of the cost-benefit analyses that agencies are currently required to perform. Also, S. 746 applies to rules issued by independent regulatory agencies that are not covered by Executive Order 12866.

However, as currently written, S. 746's analytical requirements do not appear to apply to some rules that are covered by Executive Order 12866. The executive order's cost-benefit analysis requirements apply to "economically significant" rules issued by the covered agencies, and the order defines economically significant rules as ones that are likely to have

"an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities."

Under the executive order, a rule can have a $100 million effect on the economy by imposing $100 million in costs or by providing $100 million in benefits. S. 746's cost-benefit analysis requirements apply to "major" rules, and the bill defines a major rule in subsection 621(7)as one that

"(A) the agency proposing the rule or the Director (of the Office of Management and Budget) reasonably determines is likely to have an annual effect on the economy of $100,000,000 or more in reasonably quantifiable costs; or (B) is otherwise designated a major rule by the Director on the ground that the rule is likely to adversely affect, in a material way, the economy, a sector of the economy, including small business, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments, or communities."

Therefore, a rule that is economically significant under Executive Order 12866 because it is likely to have more than $100 million in benefits (but perhaps only $90 million in costs) would not be covered by the analytical requirements in S. 746 (unless designated by the Director). Also, the bill does not cover a rule if the agency determines that it imposes $90 million in costs plus other costs that are not "reasonably quantifiable." If the intent of the bill is not to exclude these kinds of rules covered by the executive order, the definition of a major rule in subsection 621(7)(A) could be amended to eliminate the words "in reasonably quantifiable costs."

Agencies Could Improve Cost-Benefit Analyses

The centerpiece of S. 746 is its emphasis on cost-benefit analysis for major rules. The bill establishes detailed procedures for preparing those analyses and using them in the rulemaking process. Therefore, it is important to understand how agencies are currently preparing cost-benefit analyses.

Mr. Chairman, in a 1998 report prepared at your and Senator Glenn's request, we examined 20 cost-benefit analyses at 5 agencies to determine the extent to which those analyses contain the "best practices" elements recommended in the Office of Management and Budget's (OMB) January 1996 guidance for conducting cost-benefit analyses.[3] We concluded that some of these 20 analyses did not incorporate OMB's best practices. For example, the guidance states that the cost-benefit analysis should show that the agency has considered the most important alternative approaches to the problem addressed by the proposed regulatory action. However, 5 of the 20 analyses that we examined did not discuss any alternatives to the proposed action, and some of the studies that discussed alternatives did so in a limited fashion. For example, the Food and Drug Administration's (FDA) regulation on adolescents' use of tobacco examined six regulatory alternatives but contained only a few paragraphs on the five that were ultimately rejected. A more thorough discussion of the alternatives that FDA considered would have better enabled the public to understand why the agency chose the proposed action.

Six of the cost-benefit studies did not assign dollar values to benefits, and only six analyses specifically identified net benefits (benefits remaining after costs have been accounted for)—a key element in OMB's guidance. Executive Order 12866, on which OMB's guidance is based, emphasizes that agencies should select approaches that maximize net benefits unless a statute requires another regulatory approach.

The OMB guidance stresses the importance of explicitly presenting the assumptions, limitations, and uncertainties in cost-benefit analyses. However, the analyses that we examined often were not explicit or "transparent" on these matters. For example, five of the analyses did not explain why the agencies did not use a discount rate to determine the present value of future benefits and costs. Also, five of the analyses did not explain why they did not discuss the uncertainty associated with the estimated benefits and costs. Similarly, in a 1997 report examining 23 cost-benefit analyses supporting the Environmental Protection Agency's (EPA) air quality regulations, we concluded that certain key economic

[3]Regulatory Reform: Agencies Could Improve Development, Documentation, and Clarity of Regulatory Economic Analyses (GAO/RCED-98-142, May 26, 1998).

assumptions were not identified or were not explained in 8 of the analyses.[4] For example, one analysis assumed a value of life that ranged from $1.6 million to $8.5 million while another analysis that was prepared in the same year assumed a value of life that ranged from $3 million to $12 million. In neither case did the analysis clearly explain why the values were chosen.

Eight of the 20 cost-benefit analyses that we examined in our 1998 report did not include an executive summary that could help Congress, decisionmakers, the public, and other users quickly identify key information addressed in the analyses. In our 1997 report, 10 of the 23 analyses supporting air quality regulations did not have executive summaries. We have previously recommended that agencies' cost-benefit analyses contain such summaries whenever possible, identifying (1) all benefits and costs, (2) the range of uncertainties associated with the benefits and costs, and (3) a comparison of all feasible alternatives.[5]

S. 746 addresses many of these areas of concern. For example, when an agency publishes a notice of proposed rulemaking (NPRM) for a major rule, section 623 of the bill would require agencies to prepare and place in the rulemaking file an initial regulatory analysis containing an analysis of the benefits and costs of the proposed rule and an evaluation of the benefits and costs of a reasonable number of alternatives. Section 623 also requires an evaluation of the relationship of the benefits of the proposed rule to its costs, including whether the rule is likely to substantially achieve the rulemaking objective in a more cost-effective manner or with greater net benefits than other reasonable alternatives. Finally, it requires agencies to include an executive summary in the regulatory analysis that describes, among other things, the key assumptions and scientific or economic information upon which the agency relied.

Enactment of the analytical, transparency, and executive summary requirements in S. 746 would extend and underscore Congress' previous statutory requirements that agencies identify how regulatory decisions are made. We believe that Congress and the public have a right to know what alternatives the agencies considered and what assumptions they made in deciding how to regulate. Although those assumptions may legitimately

[4]Air Pollution: Information Contained in EPA's Regulatory Impact Analyses Can Be Made Clearer (GAO/RCED-97-38, Apr. 14, 1997).

[5]Cost-Benefit Analysis Can Be Useful in Assessing Environmental Regulations, Despite Limitations (GAO/RCED-84-62, Apr. 6, 1984).

vary from one analysis to another, the agencies should explain those variations.

All Major Rules Do Not Have NPRMs

If enacted, Congress may want to review the implementation of this part of S. 746 to ensure that the initial regulatory analysis requirements apply to all of the rules that it anticipated. As I previously noted, the bill's analytical requirements apply to all major rules at the time they are published as an NPRM. The Administrative Procedure Act of 1946 (APA) permits agencies to issue final rules without NPRMs when they find, for "good cause," that the procedures are impracticable, unnecessary, or contrary to the public interest.[6] When agencies use this exception, the APA requires the agencies to explicitly say so and provide an explanation for the exception's use when the rule is published in the Federal Register.

In a report we issued last April, we pointed out that 23 of the 122 final rules that were considered "major" under the Small Business Regulatory Enforcement Fairness Act and published between March 29, 1996, and March 29, 1998, were issued without a previous NPRM.[7] If the same proportion holds true for the major rules covered by S. 746, the initial analytical requirements in the bill would not apply to nearly one-fifth of all final major rules.

We also examined the issuance of final rules without NPRMs in another report that we issued last year.[8] In some of the actions that we reviewed, agencies' stated rationales for using the good cause exception were not clear or understandable. For example, in one such action, the agencies said in the preamble to the final rule that a 1993 executive order that imposed a 1994 deadline for implementation and incorporation of its policies into regulations prevented the agencies from obtaining public comments before issuing a final rule in 1995. In other actions, the agencies made only broad assertions in the preambles to the rules that an NPRM would delay the issuance of rules that were, in some general sense, in the public interest.

We believe that agencies need the flexibility to publish final rules without NPRMs in order to respond quickly to emergencies and in other

[6]An NPRM is also not required for interpretative rules; general statements of policy; or rules of agency organization, procedures, or practice.

[7]Regulatory Reform: Major Rules Submitted for Congressional Review During the First 2 Years (GAO/GGD-98-102R, Apr. 24, 1998).

[8]Federal Rulemaking: Agencies Often Published Final Actions Without Proposed Rules (GAO/GGD-98-126, Aug. 31, 1998).

appropriate situations. Similarly, we believe that using the issuance of NPRMs as the trigger for analytical requirements may be entirely appropriate. However, as a result, some major rules will probably not be subject to these requirements.

Peer Review Can Improve Regulatory Decisionmaking

S. 746 also requires agencies to provide for an independent peer review of any required risk assessments and cost-benefit analyses of major rules that the agencies or the OMB Director reasonably anticipate are likely to have a $500 million effect on the economy. Peer review is the critical evaluation of scientific and technical work products by independent experts. The bill states that the peer reviews should be conducted through panels that are "broadly representative" and involve participants with relevant expertise who are "independent of the agency."

We believe that important economic analyses should be peer reviewed. Given the uncertainties associated with predicting the future economic impacts of various regulatory alternatives, the rigorous, independent review of economic analyses should help enhance the quality, credibility, and acceptability of agencies' decisionmaking.

In our 1998 study of agencies' cost-benefit analysis methods that I mentioned previously, only 1 of the 20 analyses that we examined received an independent peer review.[9] Of the five agencies whose analyses we examined, only EPA had a formal peer review policy in place. Although OMB does not require peer reviews, the Administrator of OMB's Office of Information and Regulatory Affairs (OIRA) testified in September 1997 that the administration supports peer review. However, she also said that the administration realizes that peer review is not cost-free in terms of agencies' resources or time.

The peer review requirements in S. 746 provide agencies with substantial flexibility. If an agency head certifies that adequate peer review has already been conducted, and the OMB Director concurs, the bill requires no further peer review. However, agencies will need to carefully plan for such reviews given the bill's requirement that they be done for all risk assessments and each cost-benefit analysis for which the associated rule is expected to have a $500 million effect on the economy. Agencies will also need to ensure that a broad range of affected parties are represented on the panels and (as S. 746 requires) that panel reports reflect the diversity of opinions that exist.

[9] GAO/RCED-98-142.

Transparency of Regulatory Actions Can Be Improved

Mr. Chairman, last year we issued a report which you and Senator Glenn requested, assessing the implementation of the regulatory review transparency requirements in Executive Order 12866.[10] Those requirements are similar to the public disclosure requirements in S. 746 in that they require agencies to identify for the public the substantive changes made during the period that the rules are being reviewed by OIRA, as well as changes made at the suggestion or recommendation of OIRA. We reviewed four major rulemaking agencies' public dockets and concluded that it was usually very difficult to locate the documentation that the executive order required. In many cases, the dockets contained some evidence of changes made during or because of OIRA's review, but we could not be sure that all such changes had been documented. In other cases, the files contained no evidence of OIRA changes, and we could not tell if that meant that there had been no such changes to the rules or whether the changes were just not documented. Also, the information in the dockets for some of the rules was quite voluminous, and many did not have indexes to help the public find the required documents. Therefore, we recommended that the OIRA Administrator issue guidance on how to implement the executive order's transparency requirements.

The OIRA Administrator's comments in reaction to our recommendation appeared at odds with the requirements and intent of the executive order. Her comments may also signal a need for ongoing congressional oversight and, in some cases, greater specificity as Congress codifies agencies' public disclosure responsibilities and OIRA's role in the regulatory review process. For example, in response to our recommendation that OIRA issue guidance to agencies on how to improve the accessibility of rulemaking dockets, the Administrator said "it is not the role of OMB to advise other agencies on general matters of administrative practice." The OIRA Administrator also indicated that she believed the executive order did not require agencies to document changes made at OIRA's suggestion before a rule is formally submitted to OIRA for formal review. However, the Administrator also said that OIRA can become deeply involved in important agency rules well before they are submitted to OIRA. Therefore, adherence to her interpretation of the order would result in agencies' failing to document OIRA's early role in the rulemaking process. Those transparency requirements were put in place because of earlier congressional concerns regarding how rules were changed during the regulatory review process.

[10]Regulatory Reform: Changes Made to Agencies' Rules Are Not Always Clearly Documented (GAO/GGD-98-31, Jan. 8, 1998).

Finally, the OIRA Administrator said that an "interested individual" could identify changes made to a draft rule by comparing drafts of the rule. This position seems to change the focus of responsibility in Executive Order 12866. The order requires agencies to identify for the public changes made to draft rules. It does not place the responsibility on the public to identify changes made to agency rules. Also, comparison of a draft rule submitted for review with the draft on which OIRA concluded review would not indicate which of the changes were made at OIRA's suggestion—a specific requirement of the order.

We believe that enactment of the public disclosure requirements in S. 746 would provide a statutory foundation to help ensure the public's access to regulatory review information. In particular, the bill's requirement that these rule changes be described in a single document would make it easier for the public to understand how rules change during the review process. We are also pleased to see that S. 746 requires agencies to document when no changes were made to the rules.

Additional refinements to the bill may help clarify agencies' responsibilities in light of the OIRA Administrator's comments responding to our report. For example, S. 746 could state more specifically that agencies must document the changes made to rules at the suggestion or recommendation of OIRA whenever they occur, not just the changes made during the period of OIRA's formal review. Similarly, if Congress wants OIRA to issue guidance on how agencies can structure rulemaking dockets to facilitate public access, S. 746 may need to specifically instruct the agencies to do so.

Conclusions

S. 746 contains a number of provisions designed to improve regulatory management. These provisions strive to make the regulatory process more intelligible and accessible to the public, more effective, and better managed. Passage of S. 746 would provide a statutory foundation for such principles as openness, accountability, and sound science in rulemaking.

This Committee has been diligent in its oversight of the federal regulatory process. However, our reviews of current regulatory requirements suggest that, even if S. 746 is enacted into law, congressional oversight will continue to be important to ensure that the principles embodied in the bill are faithfully implemented.

To strengthen and promote cities as centers of opportunity, leadership, and governance.

National League of Cities

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Statement of the Honorable Gregory S. Lashutka
MAYOR of Columbus, Ohio

on behalf of

The National League Of Cities

before the

U.S. SENATE COMMITTEE ON GOVERMENTAL AFFAIRS

APRIL 21, 1999

Thank you Mr. Chairman and members of the Committee for the opportunity to provide testimony on the Regulatory Improvement Act (S. 746). I especially want to commend you, Mr. Chairman, and Sen. Levin, for your expertise and commitment to making the regulatory process more accountable to the people.

As you are aware, the City of Columbus has been a national leader in stressing the need for new federal procedures to reduce the unintended consequences of mandates and regulations on our nation's cities and towns. Not only have I weighed in on behalf of my city and citizens on Regulatory Reform, but today I am testifying on behalf of the National League of Cities. NLC is the largest and oldest organization representing the nation's cities and towns—from all of its largest to many of its smallest. We are proud that two of our past presidents are current members of the Senate, Sens. Voinovich, of this committee, and Lugar. NLC represents 135,000 cities and towns across the country. Over 75 percent of NLC's members are from small cities and towns with populations less than 50,000.

The National League of Cities strongly supports the Regulatory Improvement Act of 1999. Nor are we alone, but lead all the organizations representing the nation's state and local governments, the "Big 7," in supporting passage of legislative and regulatory goals that benefit states and local governments and their constituents. I am pleased to bring with me today a copy of a letter signed by the Presidents of all of the state and local

government associations supporting this legislation. Passage of S. 746 is a part of the federalism partnership agenda of the Big 7.

The Big 7 is also pleased to work with you and Senator Levin towards the passage of the "Regulatory Improvement Act" (S. 59) and the preemption bill that we are currently drafting. The Big 7 believes that these bills are a significant legislative package that clarify the intent of federal regulation and legislation, while allowing for further input of state and local governments in the processes. We applaud your leadership on these issues.

While the Unfunded Mandates Relief Act of 1995 has had a positive impact on the shift of the burden of costs on state and local government, it only addresses legislation. It does not address federal regulations. S. 746 will close the gap that is left open that allows for costly regulation on cities by providing for better consultation with state and local governments and for risk assessment and cost-benefit analysis of the legislation.

It is imperative that all levels of government work together to deliver the most efficient services to their constituents. Our constituents expect federal, state, and local governments to function together and provide effective service. The most effective way for all of us to deliver our services is for each level of government to stay within its most effective and efficient roles. These lines are becoming more and more obscure as the federal government continues to regulate the various sectors of our local communities

without consideration of the impact of its actions. Gaining an equal voice in the regulatory process allows for cities and towns to demonstrate the impacts before it is too late.

We must balance the health, safety, and economic needs and wants of all our citizens. Here's the core of the problem. Each Washington bureaucracy or Congressional subcommittee views our cities through straws. They only look at one thing at a time. For example, as we promote regulations on underground storage tanks, that's one set. And yet, that may or may not correlate, and usually doesn't, with stormwater runoff, or how we're going to pursue the issue on drinking water, or trucker safety. We are a microcosm that interacts--a living, breathing, dynamic region—and not just a government, but businesses—small, medium and large. We look to for economic energy and tax dollars. And all of these mandates have an impact, good or bad, upon us. Sometimes they do have a rational and scientific based relationship. Sometimes they don't. The problem, in my opinion, is tunnel vision. And that is one of the greatest problems we will have as we look for changes in the federal government. Each regulation may take just a few pages in the Federal Register, but everything gets aggregated at the local level. We somehow have to implement everything that applies to us that comes in the Federal Register. Very few people that we see in Washington make any effort to see how they interrelate.

In the past year, our cities and towns have seen regulations that preempt our cities and towns decision-making authority on local issues and regulations that have cost our cities millions if not billions of dollars.

For example, the Occupational Health and Safety Administration (OSHA) mandated that cities who were in OSHA state plan states would have to following "manning" standards to respond to interior structural fires. Cities and towns support efforts to implement regulations to support the greater need for health, safety, and the environment. But, this regulation was implemented at a period when fires have been at an historical low.

While many of our cities are able to comply with the standard, the smaller cities and towns are faced with a bigger burden and very little alternatives short of hiring additional staff or increasing hours for fire fighters. These cities and towns are struck with a disproportionate burden and little guidance and then forced to make a choice about how to fund the mandate. For cities and towns, we have to decide between the lesser of two evils: cutting services in other areas or increasing taxes. Implementation of S. 746 would have enabled more local government input in the rulemaking process and a careful consideration of the costs and benefits of this regulation.

This is not to say that regulations are not important, but it is meant to say it is extremely important that any community fully understand that trade-offs do occur and any federal or state regulation in the areas of environmental, transportation, labor, education have consequences on the community. But the key point is, local government understands much more about problems in our communities that threaten the health and safety of our citizens than a bureaucracy in Washington. We must be involved in

providing solutions. That is why we support your premise in the Regulatory Improvement Act.

The Regulatory Improvement Act is based on a simple premise: people have a right to know which government agencies make the most important and expensive regulatory decisions. The Regulatory Improvement Act not only gives people the right to know: it gives them the right to see, to see how government works, or how it doesn't.

Nearly three years ago, the Treasury promulgated regulations on states and local governments that were retroactive. Like many IRS regulations, these were nearly indecipherable. They dealt with a seemingly arcane topic called "yield burning." The bottom line, was that these regulations proposed vast authority for the Internal Revenue Service to conduct audits of state and local tax-exempt bond refinancings done between 1991 and 1995—a period when interest rates dropped dramatically, and many governments as well as homeowners and businesses refinanced their outstanding debt-to determine if those states and local governments had paid the underwriters too much for the millions of dollars of savings they achieved for their taxpayers.

Understand, we were dealing with transactions long since completed; transactions done without any clear guidelines from the federal regulatory agency at the time they were done; and guidelines involving perceived abuses by the private—not the public state and local governments. Moreover, because Secretary Rubin has recused himself from these regulations, due to his association with an underwriter at the time of these

transactions, the IRS regional offices have pursued audits and investigations of state and local governments without any clear guidance. They have advised us that if the federal regulators determine that it is the underwriter who has done wrong, in their eyes, and that the city or state is an innocent victim, then the city or state may make a large financial settlement with the IRS, hire its own attorney, and file suit in federal court against the underwriter.

The Big 7, Mr. Chairman, has met with the Assistant Secretary for Tax Policy, the Chairman of the Securities and Exchange Commission, and the Vice President on this issue. We have never received an answer from any of the three. The issue continues. As recently as two weeks ago, we made an inquiry to the Treasury. The response was that no one seemed to know who was in charge, when—if ever—there would be a response, much less how such actions comported with any federal-state-local partnership.

Just last week, the Clinton Administration withdrew a controversial proposed fair housing rule from the Department of Housing and Urban Development (HUD). The rule would have granted HUD unilateral, unbridled, and unchecked authority to determine whether a city or state has cured impediments to fair housing, both within and outside of its own legal authority and control. HUD never consulted local governments in the drafting process. While NLC applauds the Administration's action in this case by allowing local governments to sit down at the table with the regulators to discuss the issue and draft reasonable regulations, S. 746 would have ensured that this consultation occurred in the first place—not after the fact. We must ensure that the partnership of

federal, state, and local government realizes the needs and concerns of our communities. That is precisely what regulatory reform would mean.

It is imperative that as we go into the 21st century, we improve public confidence. We have learned that it is imperative that, for us, as a community to improve our communities' overall quality of life, we give up control and return decision making to our citizens. This is an extremely difficult task to accomplish, because errors in judgment will be made. However, if we are truly to proceed with improving our citizens quality of life there is no other way to reach this goal. Improvements in health, safety and environmental quality are only going to be realized by changing behaviors of the individuals that live in our communities, not by telling them what to do. This requires trust, as well as accurate and timely information.

Our federal government can establish the mechanism for providing accurate and timely information. It can be a key partner. S. 746 makes a critical step in that direction. It proposes relaxing the command and control mentality to trust state and local governments to create the environment of partnership that will lead to our improved quality of life initiative as we do with our own citizens.

I sincerely thank you for this opportunity to express my views on this important governance issue, and as always I will be glad to response to any questions you may have at the appropriate time.

ECOS

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Statement of
Robert E. Roberts
Executive Director
The Environmental Council of States

before the

Governmental Affairs Committee
United States Senate

on the

Regulatory Improvement Act of 1999

on behalf of
The Environmental Council of States

April 21, 1999

Mr. Chairman and Members of the Committee:

Thank you for the opportunity to appear before you this morning regarding the Regulatory Improvement Act of 1999. My name is Robbie Roberts, and I am the executive director of the Environmental Council of States (ECOS). The Environmental Council of States is the national non-partisan, non-profit association of state and territorial environmental commissioners. Each State and territory has some agency, called different things in different states, and located in different places in different state governments, that corresponds to the United States Environmental Protection Agency. Our members are the States and territories and the people with whom we work are the officials who manage the environmental agencies in the States and territories. Currently, 52 of the 55 States and Territories are members of ECOS.

We are delighted to join with our friends and colleagues in the National Governors' Association, the Council of State Governments, the National Conference of State Legislatures, the National Association of Counties, the US Conference of Mayors, and the National League of Cities to support this legislation.

Robert W. Varney is the Commissioner of the New Hampshire Department of Environmental Services and the current President of ECOS. He regrets that he could not be with you today, but asks that I formally present the letter that is attached to this testimony.

I would like to read one paragraph of Commissioner Varney's letter which, I would argue, captures the central issues in this proposed legislation.

> "We support the consideration of cost benefit analysis, because to do otherwise is to risk misapplication of limited resources. We support risk analysis because to do otherwise may be to attack the wrong problems. Expanding the participation of state and local government officials in the development of national environmental requirements can only strengthen the final products."

Mr. Chairman, the extent to which environmental protection is performed not by the federal government but by the States and local governments is not, perhaps, generally understood. Let me give you four measures of the degree to which environmental responsibilities have been shifted to the States:

- Approximately 75% of state environmental and natural resources spending is state funds, not federal funds.
- 78% of enforcement actions are taken by state environmental officials, not federal environmental officials.

- About 96% of the total environmental quality information currently held in government databases was gathered by state environmental officials, not federal environmental officials.

- And of all the major environmental programs that were designed to be delegated to the States, approximately 71% have been delegated and are being administered by the States.

This is a success story. We have talked over the last few years about devolution of responsibility to the States; much of the devolution has already taken place. As States have increased their capacity and as environmental protection has become increasingly important to the general public, more and more responsibilities have been moved to the level of government best able to carry them out – State and local governments – which are "best able" because they are closest to the problems, closest to the people who must solve the problems, and closest to the communities which must live with the solutions.

In this situation, it becomes increasingly important that taxpayer resources be directed to the most important problems. Problems sometimes seem to be infinite. Resources are finite. To help prioritize problems and define where to apply limited resources, new and innovative techniques are required. Risk analysis and benefit – cost analysis of proposed federal rules and regulations can improve our ability to spend taxpayers' money wisely.

Finally, we support actions which make the federal rule-making process easier to understand and easier to participate in. By making more information available, all interested participants – including state and local government officials – can help assure that rules and regulations better meet the needs of the local area and of the Nation.

Thank you, Mr. Chairman, for this opportunity.

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April 16, 1999

The Honorable Fred Thompson
Chairman, Committee on Governmental Affairs
United States Senate
Washington, DC 20510 – 6250

Dear Mr. Chairman:

The Environmental Council of the States (ECOS) joins you in supporting requirements for cost benefit analysis and risk assessment in the development and promulgation of major rules. ECOS is the national non-partisan, non-profit association of state and territorial environmental commissioners.

We support the consideration of cost benefit analysis, because to do otherwise is to risk mis-application of limited resources. We support risk analysis because to do otherwise is to attack the wrong problems. Expanding the participation of state and local government officials in the development of national environmental requirements can only strengthen the final products.

The unanimity of support you have obtained from the National Governors' Association, the National League of Cities, the Council of State Governments, the National Conference of State Legislatures, the U. S. Conference of Mayors and the National Association of Counties demonstrates how important this issue is to elected officials. I hasten to assure you that it is equally important to those appointed officials who carry out the day-to-day management of the states environmental programs.

Sincerely,

Robert W. Varney
Commissioner
New Hampshire Department of Environmental Services
President, Environmental Council of the States

Please note that a similar letter was sent to Senator Levin.

Testimony
Of
Scott Holman
On Behalf of
The U.S. Chamber of Commerce
before the
Committee on Governmental Affairs
U.S. Senate
on
S. 746, The Regulatory Improvement Act
April 21, 1999

Chairman Thompson, Ranking Member Lieberman, and members of the Committee on Governmental Affairs, I am Scott Holman, owner and President of Bay Cast Inc. of Bay City, Michigan. My company is a small manufacturer of large custom steel castings for the automotive tooling, machine tool, steel mill and construction industries.

I am a member of the U.S. Chamber of Commerce's (the "Chamber") Board of Directors and Small Business Council. Additionally, I am Chairman of the Chamber's Regulatory Affairs Committee. I was also a delegate to the 1995 White House Conference on Small Business and served as the Michigan State Chair for both the regulatory and taxation committees.

I would like to thank you for the opportunity to testify on behalf of the Chamber, of which more than 96 percent of the members are small businesses, 71 percent of which have 10 or fewer employees. Therefore, we are particularly cognizant of the problems of smaller businesses.

Mr. Chairman, first, I would like to salute you, and, my Senator, Mr. Levin, for your leadership to make the federal regulatory process more accountable and responsive to the

regulated community, which includes all Americans. The growing spirit of bipartisanship in Congress for improving the regulatory system is very encouraging to me. Along with the Regulatory Improvement Act, the Mandates Information Act, the Regulatory Right-to-Know Act, and the Small Business Paperwork Reduction Act are all examples of both parties coming together to help provide some common sense rationality to the fragmented and overly complex regulatory system with which small businesses must deal.

Regulation and Small Business

Government paperwork, red tape and regulations are among the greatest concerns facing small business owners today. The regulatory burdens imposed on businesses in the United States are astounding. Recent studies estimate the compliance costs of federal regulations at more than $700 billion annually, and project substantial future growth even without the enactment of any new legislation. These costs are passed along in the form of higher prices and taxes, reduced wages, stunted economic growth, and decreased technological innovation.

Worse yet, the smaller the business, the more dramatic the cost. According to the U.S. Small Business Administration, small businesses represent about 99% of all employers. Yet a 1995 study conducted by renowned economist Tom Hopkins found that businesses with fewer than 20 employees have almost **twice** the regulatory costs per employee than operations with 500 or more employees.[1] Small businesses clearly play such a key role in our society. According to

[1] Thomas D. Hopkins, Profiles of Regulatory Costs, A Report to the U.S. Small Business Administration, November 1995.

the SBA, almost 57% of working Americans are employed in small companies, and small companies account for over 52% of national annual sales.

There are several reasons why smaller business bears a heavier regulatory burden than larger businesses. One reason has to do with the fixed costs. Fixed costs are independent of output, i.e. any company affected by the regulation pays the same fixed costs. An example of fixed costs would be a requirement that every firm submit a lengthy quarterly report to a regulatory agency. It would cost every firm the same amount to complete the report. However, the larger companies can spread the fixed cost over large quantities of output. Put simply, small businesses because of economies of scale are not equipped to deal with the one-size fits all approach to federal regulations.

Additionally, walk into any small business and look for the accounting department, the legal counsel, or the human resources division. You will not find them. Small businesses just do not have the staff time, resources, experts, and money to help them figure out the federal regulatory labyrinth.

A 1994 Harvard University study concluded that more than 60,000 lives are lost due to misplaced priorities of the current command-and-control regulatory system. [2] The current regulatory system spends billions of dollars on eliminating negligible or nonexistent risks. Meanwhile, regulators are failing to protect the public from other risks that are much more serious. An example discussed in the study compared two approaches to preventing cancer. The

federal government regulates emissions of the suspected carcinogen benzene during waste operations at an estimated cost of $19 million per life saved. However, a highly proven life saving method that costs approximately $17,000 per life saved, the mammogram, is not regularly administered to 70 percent of women over the age of fifty. [3]

Regulation and My Small Business

I, like the other small businesses across our nation, find it frustrating that regulators can't seem to figure out that federal regulations and paperwork cost not only time but time spent figuring out how to comply.

Many regulations continue to impede the ability of small businesses to compete in the emerging global economy. In my industry alone, the average company must complete 13 routine environmental reporting and record keeping requirements. It can take a single casting plant, like mine, 590 hours or nearly 15 work weeks to comply with these regulations, and this figure does not include OSHA reporting requirements.

For example, a regulation relevant to just one of the many raw materials used in metalcasting industry deals with sand. Every year, foundries use more than 100 million tons of this material. Approximately 90-95 percent of the used foundry sand is not toxic when tested by the method EPA requires to determine toxicity, called the toxicity characteristic leaching

[2] Tengs, Tammy O., "Optimizing Societal Investments in the Prevention of Premature Death," doctoral dissertation, School of Public Health, Harvard University, June 1994, p.2

procedure (TCLP), under the Resource Conservation and Recovery Act (RCRA). That 5%-10% portion of the used sand universe that fails to pass the toxicity test is easily identifiable by a specific production process that is its source, so the hazardous portion could easily be disposed of differently than the non-hazardous portion. Unfortunately, the regulation does not allow us the flexibility to do the sensible thing.

In fact, an independent study conducted in Wisconsin showed used foundry sand to be less of a threat to the environment or human health than even natural background soils. This material is a commodity that can be made available for reuse in numerous construction-related applications. Technology also exists to convert used foundry sand into glass for use in roofing and other materials. Yet foundries across the nation face tremendous hurdles in getting approval for beneficial reuses of this byproduct of their process, so foundries end up paying ever-increasing disposal costs for sand.

The burdens imposed by these restrictions amount to significant costs for small facilities like mine. Instead of building incentives into our regulations that allow small metalcasters to make investments that increase productivity, restrictions are imposed on both foundry sand reuse as well as disposal. Disposal costs for these and other reusable materials totals approximately $500 million for the industry -- depending on the landfill tonnage fees at the time. This is too much to pay for materials that have been judged to be "cleaner than dirt."

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[3] Tengs, Tammy O. and Graham, John D., "The Opportunity Costs of Haphazard Social Investments in Life-Saving," Risk, Costs, and Lives Saved, Editor: Robert W. Hahn, The AEI Press, Washington, D.C., 1996, p.167

It is sad and ironic that our society and small metalcasters are forced to pay a double cost because of this excessive regulation: we lose the opportunity to convert the sand into useful economic items, and we must instead pay the high cost of needless disposal. So the sand fills up valuable landfill space, while it could have been recycled and used to make new products. Is this an environmentally friendly regulation?

The Regulatory Improvement Act of 1999 and Small Business

Information is power. This has never been as true as it is in today's "information age." S. 746 is about ensuring a healthy exchange of information on governmental decisions between the People and their government. One of the founding principles of our Nation was the ability of People to question their government. The Regulatory Improvement Act of 1999 provides power to the American people through greater information.

There are many things that can be done to ease the burden of regulations on the backs of small businesses. An effective tool in the war against excessive regulation would be requiring federal regulators to use cost-benefit analyses when writing their rules. The federal government often implements new regulations without any thought or recognition of the costs imposed on businesses and jobs.

Small Business owners believe that proposed regulations that address, health, safety, or environmental risks should be grounded in principles that provide for honest, objective risk assessment and risk management. I, as a member of the Bay City community, want a safe and healthy environment for my own and my employees' families. The inclusion of risk assessments

into the regulatory record will provide more transparency into how government reaches its decisions and will produce better-informed decision making and build the confidence of the public that the most serious problems are being addressed.

S. 746 would require the federal agencies to conduct regulatory analyses, including cost-benefit analysis, and, if relevant, a risk assessment, when issuing new regulations that have an annual economic impact of $100 million or that have other significant impacts. The analysis must determine whether the benefits of the rule justify the costs; whether the rule is cost-effective; and whether the rule adopts a flexible regulatory option, such as market- or performance based incentives. If the agency determines that the rule does not do so, the agency must explain the reasons why it selected a rule.

In presenting a cost-benefit analysis and risk assessment, the rulemaking agency must present the results of the analysis and assessment in a clear and understandable form, including an executive summary of the expected benefits and costs of the rule and the agency's cost-benefit determinations; the risk addressed by the rule and the results of any risk assessment; the benefits and costs of other regulatory options considered by agency; and the key assumptions and scientific or economic information upon which the agency relied. The regulatory analysis provided by S. 746 would have been helpful to me and others -- perhaps the "sand disposal" rule I discussed could have ensured greater environmental protection and been more cost-effective.

Improving the quality of government decision-making and providing greater public participation in the regulatory process would enhance the efficacy and value of regulations for

small businesses and the entire regulated community. Furthermore, the Chamber strongly believes peer reviewed and publicly scrutinized risk assessment and cost-benefit analyses must be used to set national priorities and target resources at critical hazards where the greatest public benefit can be achieved. Let's not forget a tax dollar spent on a wasteful program is a tax dollar that can not be spent on more teachers, police officers, and health care.

Many of the regulations and paperwork requirements that have frustrated small business owners, such as myself, come from laws which are dated and need to be reviewed, or by laws that simply restrict small business owners for no good purpose, such as my sand rule example. Recognizing this problem, Congress passed the Regulatory Flexibility Act (RFA) in 1980 and further improved through the Small Business Regulatory Enforcement Act (SBREFA) in 1996. The purpose of these laws is to enhance the ability of small business to comply with federal mandates. S. 746 would take another big step towards helping small businesses by ensuring well thoughtout regulations, which maximize protection and minimize costs.

Concerns

While S.746 is a good piece of legislation, there are some areas that could be improved. We believe normal Administrative Procedure Act (APA) judicial review should apply to rulemakings following the passage of this legislation, the same as it applies to other laws. Furthermore, we are unaware of the legislative record stating that APA judicial review is broken. Nevertheless, the Chamber looks forward to working with the Members of this Committee in order to clarify how this provision works and to ensure prior rights of judicial review for cost/benefit analyses and risk assessments are not abridged.

Furthermore, the Chamber believes that the Regulatory Improvement Act would greatly improve all regulations, making them both more effective and cost-efficient. Therefore, it is our belief that no regulations should not be excluded from the provisions of this legislation. Again, the Chamber looks forward to working with the lawmakers on this panel on this issue.

Conclusion

The committee deserves to be commended for its efforts to provide greater accountability and better decision making into the regulatory process, and the Chamber appreciates the difficulties involved in pursuing this reform. We encourage the committee to continue working toward reform this year, so that these crucial reforms will become law.

TESTIMONY OF RONALD A. CASS
DEAN AND MELVILLE MADISON BIGELOW PROFESSOR OF LAW
BOSTON UNIVERSITY SCHOOL OF LAW

April 19, 1999

The Honorable Fred Thompson, Chairman
Senate Governmental Affairs Committee
Room SD-340
Washington, D.C. 20510

Dear Mr. Chairman:

The following comments respecting The Regulatory Improvement Act of 1999, Senate Bill S. 746, represent the personal views of Ronald A. Cass, Dean and Melville Madison Bigelow Professor of Law at Boston University School of Law. I have practiced in the fields of Administrative Law and Regulation for more than twenty-five years and have taught and written about these fields for more than twenty years. I have represented regulated entities and have served in government as an attorney and as a Presidential appointee. I have served as both a Public Member and a Government Member of the former Administrative Conference of the United States, as well as a consultant to that agency, and I currently am Chair of the Section of Administrative Law and Regulatory Practice of the American Bar Association. These comments reflect my own experience and judgments. Last year, the Section of Administrative Law and Regulatory Practice submitted comments on behalf of the American Bar Association. My remarks build on that submission, but today's comments are solely on my own behalf and have neither been submitted to nor approved by the American Bar Association.

Overview: Rulemaking Process Requirements

The bill before your Committee, S. 746, would improve the efficiency and fairness of the regulatory process and would help align administrative decisions with the public interest. Those are the essential goals of administrative process. There are ways in which the bill might be improved—one specific suggestion is offered below—but the overall contribution of this proposed legislation is significant and positive.

With the passage of the Administrative Procedure Act of 1946, Congress endeavored to lay out a framework for agency decision-making that provided uniformity across agencies at a general level, while allowing some variations to account for differences across agencies, decisions, and circumstances. Over the past five decades, the scope of agency authority has expanded, the number of statutory instructions has grown, and the number of settings in which agencies have been called upon to make legislative-type decisions in order to implement congressional directives has increased.

Agency rulemaking has become the principal mechanism for instituting new initiatives within an agency's legislative authority, for articulating the contours of that authority as the agency sees it, for announcing and for altering agency policy. Agencies turned to rulemaking because it allows them to gain information from an array of parties affected by agency policy setting rather than the few parties who might be directly represented in an adjudication. For rulemaking to serve its intended function, it should be conducted in a manner that gives fair notice to those who will be affected by the agency action, that produces accurate information on the important issues relevant to the regulatory decision in question, and that facilitates sound analysis of the information.

As agency reliance on rulemaking has grown—and as the impact of agency rulemaking on the economy and our society has increased—we have paid greater attention to problems that can be created if agency rules are insufficiently attentive to particular effects. Periodically, Congress has specified ways in which agency rulemaking could be improved at least with respect to a given consideration. Sometimes legislative instructions have been directed to a single agency or program; sometimes they have been directed to all agencies.

The natural fear of new legislation seeking to correct perceived defects in current regulatory (especially rulemaking) processes is that, by adding yet another set of requirements, it will so encumber the rulemaking process as to frustrate beneficial rulemaking. That might occur because the legislation would require procedures that are unduly costly or because the legislation would require procedures that tilt determinations away from socially beneficial results.

Although such fears no doubt will be raised by this legislation as by other process reform efforts, I do not believe that the fears are well grounded here as the provisions of S. 746 generally should make agency rulemaking correspond more closely to public interest. The changes S. 746 would effect primarily ask that agencies attend to considerations that should be relevant to regulatory rulemaking, that agencies assess critically information pertinent to their rulemaking decisions, and that agencies allow these assessments to be open to the sort of comparative evaluation common in other venues for similar analysis. While some changes might improve the legislation, S. 746 should make government work better, respond to problems more thoughtfully, and strike an appropriate balance between the concerns regulatory interventions address and the costs such interventions impose on our society.

Rulemaking Improvements: Contributions of S. 746

General Considerations. S. 746 appears well-designed to improve rulemaking procedures and to assure that the information on which rulemaking decisions rest is appropriate to the decision-making task. The legislation would make incremental, not

sweeping, changes, building on approaches to rulemaking that are familiar to administrative lawyers.

Some of the provisions in S. 746 duplicate requirements already in place to a significant extent. For example, many programs for cost-benefit analysis and risk assessment already are in place for major agency rulemakings as a result of legislative mandates, executive orders, or agency choice.

S. 746, however, both would increase uniformity of such analyses across agencies and promote improvements in some agency analyses. Other principal reforms of the regulatory process contained in S. 746—provision for systematic review of agency rules and the codification of oversight functions in the Office of Management and Budget's Office of Information and Regulatory Analysis (OIRA)—also should improve the regulatory process.

These changes do not alter the basic structure of rulemaking or eliminate the allocation of responsibility to agencies to exercise judgment in individual rulemaking decisions within parameters of their particular legislative mandates. S. 746 generally does not, and should not, change the assignment of judicial responsibility to see that agencies stay within the limits of the law and that agency decisions meet minimal requirements of reasonableness.

By its very nature, rulemaking—like legislating—frequently will be controversial. It spells out the terms of agency policy on a range of issues including many on which knowledgeable persons have divergent views of what action will best advance the public interest. Some criticism of agency rulemaking is predicated on simple disagreement over where public interests lie and how various policies would affect them.

Some agency rulemaking, however, legitimately can be criticized for failing to gather, evaluate, and integrate information into a decision that meaningfully weighs the factors that should inform an administrative action. Some agency programs seem destined to produce little public benefit at great cost (private as well as public); other programs might appear too modest, generating large benefits at low costs and seemingly offering the prospect that more could be obtained with little additional investment.

The variance among agency regulatory decisions emerges clearly in estimates of the costs of various government health and safety programs that are intended protect human life relative to their life-saving effects. As Supreme Court Justice Stephen Breyer observed in his Holmes Lectures, the 1992 compilation of *The Regulatory Program of the United States Government* shows estimates of cost per premature death avoided that range from one hundred thousand dollars ($100,000) for regulations such as the passive restraint-seat belt rule adopted by the National Highway Traffic Safety Administration in 1985 to five trillion-seven hundred

billion dollars ($5,700,000,000,000) for the Environmental Protection Agency's 1990 rule on hazardous waste listing for wood-preserving chemicals.

No analytical tool can provide comfort in specifying what investment is appropriate to protect life and health. That is why Congress has not directed administrative agencies to draw precise lines, such as imposing regulatory requirements only if their expected annual cost per life is less than the median annual income of Americans that year. S. 746 does not substitute such nostrums for sound judgment. Instead, it addresses procedures that can facilitate such judgments. The principal provisions of S. 746—by requiring explicit attention to the costs and benefits of major regulations, by providing guidelines for risk assessments, and by encouraging peer review of risk assessments and cost-benefit analyses—should improve rulemaking decisions without imposing unnecessary costs on the process or undue impediments to needed rules.

Regulatory Analysis. The regulatory analysis mandated by S. 746 for major rules appears to be designed appropriately to encourage agency attention to the questions of cost and benefit that should be asked whenever agencies act.

Critics of cost-benefit analysis routinely express their concerns that cost-benefit analysis overemphasizes readily quantified variables and slights variables, like environmental quality, that are less readily subject to quantitative valuation. Insofar as that is true, it certainly is a legitimate source of concern.

Yet, there is nothing in the nature of cost-benefit analysis that makes this assertion true. Some cost-benefit analyses may at times undervalue less readily quantified variables, but others may at times *over*value such variables. What is true is *not* that cost-benefit analysis leads to undervaluation of what often are referred to as "soft variables"—rather, it is that rightly done, cost-benefit analysis must be sensitive to comparing costs *or* benefits that can be quantified with relative certainty to costs or benefits that cannot. Moreover, the greater the variance in estimates (again, of costs *or* benefit), the more important it is to assure that decisions are based on "apples-to-apples" comparisons. Comparing a mid-point estimate of costs to *either* an upper-bound or a lower-bound estimate of benefits plainly will skew the result in a cost-benefit analysis. But when a key variable cannot be quantified reliably, the best a decision-maker can do is to assure that he has examined the *relevant ranges* of costs and benefits carefully, based on the best information available to him.

Cost-benefit analysis is a useful tool for asking the question that is inevitably presented in assessing contemplated government actions. The form in which the question is asked may vary, but any action must be predicated on an understanding of the gain and loss associated with it. S. 746 does not make formal cost-benefit analysis the sole input to agency decision-making, and the bill properly cautions attention to nonquantifiable as well as quantifiable variables. The regulatory analysis called for by S. 746, in sum, seems well

designed to help frame issues relevant to the agency's decision. Further, analysis similar to that required by S. 746 already is required by law or by Executive Order for many of the actions that would be subject to S. 746's regulatory analysis mandate, and much agency rulemaking not subject to those requirements has been informed by analytic exercises that are roughly comparable to the cost-benefit analysis required here. In significant measure, S. 746 codifies and unifies current agency practice, while slightly expanding the scope of actions subject to such practice.

If there is residual concern about the cost-benefit analysis required by S. 746, two explanations seem plausible. One is that the concern is not with the formal structure of cost-benefit analysis but instead is focused on the sincerity with which cost-benefit analyses will be done. That concern, however, is truly independent of the *mode* of regulatory analysis. It is a concern over the regulatory decision-makers. But S. 746 leaves the locus of regulatory decision-making where it presently is assigned. Hence, this cannot be a concern that should impede passage of the legislation.

The other possible concern over cost-benefit analysis might be that a focus on costs of regulation relative to benefits will frustrate some regulation that otherwise would be adopted. If that is so, it must be because the costs will be seen demonstrably to outweigh the benefits of the particular regulation. Of course, that is the point of a cost-benefit analysis: to make certain that regulation is not imposed when its benefits are plainly less than its costs. It is worth emphasizing again that this function is entirely symmetrical: cost-benefit analysis *also* makes it more likely that regulation will not abjured when its costs are plainly less than its benefits. Here, too, the concern with S. 746's cost-benefit analysis requirement seems misplaced.

Risk Assessment. Concerns similar to those addressed to cost-benefit analysis also have been expressed with respect to risk assessment. Here, the concerns have somewhat greater force because the common subjects of risk assessment – health, safety, and environmental risks – frequently require judgments on matters of science that divide the scientific community and on values that lack ready market-based reference points.

Concerns should be muted, however, by the modesty of S. 746's requirement with respect to risk assessment. Risk assessments are required in only quite limited circumstances, and those are the circumstances most apt to be enlightened by this form of analysis. The risk assessment principles in S. 746 are fairly general; they do not handcuff regulatory agencies but merely promote better informed decision-making. No analytical process can assure that agency decisions will be sound or that all of the most interested and informed parties will approve of them. But the requirement of thoughtful risk assessments, including explanations of the critical assumptions behind the agency's analysis of scientific evidence, is designed to improve the information relied on by agency's and the communication of agency decisions to the interested public.

Peer Review. In general, S. 746's basic framework for peer review of regulatory analyses appears sensible and desirable. Peer review can help assure that regulatory analyses and risk assessments are performed in a competent, professional manner, but it is important that peer review not become in effect a trial *de novo* on the issues analyzed by the agency. That would risk extending what already is often a too-lengthy rulemaking process and also would raise legitimate concerns respecting the power conferred on individuals who are not selected in the same manner as public officials. Peer review is best seen as a very modest check that the analyses performed by regulatory agency officials conform to basic professional standards.

Judicial Review. The judicial review provision in S. 746 seems well-tailored, neither insulating considerations that make regulatory analysis sound or unsound from review nor allowing judicial review to become a strategic tool of interests opposed to agency action. The relevant section, § 627 (in combination with §§ 622 and 634), provides: (1) that regulatory analysis and risk assessment are subject to judicial review only in the context of final review of agency action, (2) that regulatory analysis and risk assessment are not evaluated separately on review but are part of the overall record, (3) that OIRA decisions respecting a rule's status as a "major rule" are not subject to judicial review, (4) that, in reviewing an agency determination whether a rule is a major rule, the party challenging the agency decision bears the burden of persuasion, and (5) that court action based strictly on the regulatory analysis or risk assessment is limited to a finding whether the analysis or risk assessment was performed, not whether it was performed in the way a judge believes best. These judgments seem sound, and the legislation -with one minor exception- seems well-designed to implement them.

The one minor amendment I would recommend is to § 627(e). The intent of this subsection appears to be this: to provide an avenue for courts, where appropriate, to instruct an agency that has failed to comply with the regulatory analysis requirements of this legislation that the law applies and that the agency must conduct the specific regulatory analysis mandated; but not to provide an avenue for review of the substance of the regulatory analysis *apart from the substantive review already authorized by law*. This meaning is evident when § 627(e) is read together with § 627(d). That reading is reinforced by § 622.

The problem with § 627(e) as drafted comes from the second sentence of the paragraph, which states "The adequacy of compliance with the specific requirements of this subchapter shall not otherwise [referring to the prior sentence respecting agency failure to perform the required analysis or to allow for peer review] be grounds for remanding or invalidating a rule under this subchapter." This phrasing could allow confusion, perhaps causing some courts to wonder whether § 627(e) in some way changes the instruction in § 627(d) that the regulatory analysis becomes part of the rulemaking record and is evaluated along with the record as a whole in determining whether the rule meets the legal standard set out in § 706 of the Administrative Procedure Act.

This confusion could be avoided by adding at the end of the sentence quoted from § 627(e) the words: "except as provided in § 627(d)." That would make plain that, so long as an agency complies with the requirement that it perform a given regulatory analysis, the adequacy of that analysis is not subject to judicial scrutiny *separate from* the court's consideration whether the rule is sufficiently supported by the record *including* the regulatory analysis to pass muster under the applicable standard of review for the rule—the standard that would apply before enactment of S. 746 and that would apply to rulemaking efforts in general.

Executive Review. Finally, the provision for Presidential review through the Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget, provides a basis for assuring that agencies attend to the concerns of all segments of society and do not slight some interests that might be less likely to be voiced effectively at the agency than at a bureau more closely overseen by the President. Currently, the functions assigned to the Administrator (and those assigned in the first instance to the President or to the Director of the Office of Management and Budget) are largely performed under the auspices of Executive Order 12866 (and previously under Executive Orders 12291 and 12498). The Executive Order, however, applies only to agencies in the Executive Branch and not to what normally are denominated "independent agencies" (those formally established outside direct presidential supervision). S. 746 would put all federal agencies onto the same footing, excepting only specific exercises of rulemaking power the outputs of which are excluded from the definition of "rule" in § 621 (10).

Conclusion

I believe strongly that this bill would improve the administrative process and strengthen the basis on which agency rulemaking actions are taken. There may be some additional cost to agency action from this legislation, as process requirements often do generate added cost. It is not apparent, however, that any added cost is a net increase over what *should* be incurred at present, as this legislation principally makes explicit requirements for obtaining reliable information and testing it to assure its reliability that should be implicit in current regulatory requirements. Insofar as making those requirements express increases cost, it must do so by inducing greater attention to exactly the sorts of information we should all want agencies to consider.

Thank you for your consideration. I hope these comments will be of use.

Sincerely,

Ronald A. Cass

Dr. Lester M. Crawford
Director, Center for Food and Nutrition Policy
Georgetown University
Presenting Testimony on
S. 746, "Regulatory Improvement Act of 1999"
Senate Committee on Governmental Affairs
April 21, 1999

I am Lester M. Crawford. My current position is that of Director of the Center for Food and Nutrition Policy at Georgetown University. Our Center operates a graduate program and conducts the Ceres Forum, a series of conferences and other mechanisms designed to analyze and report on complex issues in food and nutrition policy. From 1978 to 1991, I served in the Federal government in a number of positions relating to food safety. These were Director of the Center for Veterinary Medicine at the Food and Drug Administration and Administrator of the Food Safety and Inspection Service of the United States Department of Agriculture. I currently serve on the Expert Advisory Panel on Food Safety to the World Health Organization and on the Committee on Scientific Freedom and Responsibility of the American Association for the Advancement of Science.

I have read and am conversant with S. 746, the "Regulatory Improvement Act of 1999." I appreciate having been asked to give testimony on the bill. In my remarks, I will concentrate primarily on the relationship of S. 746 to food safety.

I previously testified on the predecessor to S. 746 which was numbered S. 981 and named the "Regulatory Improvement Act of 1998. In that testimony I mentioned some possible improvements in the bill primarily related to ensuring that the mechanisms prescribed by the bill did not in any way impede public health measures. I am pleased to note that those concerns have been adequately addressed by more explicit language in S. 981. The bill as currently written therefore meets my objectives and I would enthusiastically encourage its passage. I also am most pleased to learn that the Administration has concurred that S. 746 meets its objectives.

In my view and based on my experience, the bill would remedy a pernicious problem that has increasingly bedeviled the US rule-making process. That problem is a lack of rigor that gives rise to an absence of transparency in decision-making at many of the steps in the regulation development process especially including the role of the Office of Information and Regulatory Affairs (OIRA). Absence of transparency can occasion delay, denial and politicization or at least the suspicion thereof. At this point, I should point out that I am not condemning any particular administration; I have worked more with the four adminstrations that preceded the present one.

The hallmark of the World Trade Organization (WTO) treaty is transparency. Briefly described, the concept of transparency embraces openness, fairness and a detailed description of the decision making process. For matters involving public health, it furthermore implies that the decision will be science-based. Transparency is a standard we now demand of all other nations. The current trade disputes between Europe and the US are essentially over science-based decision-making that can only be evaluated in the presence of transparency. If transparency is required of our trading partners, it is axiomatic that we must operate in a like manner. To do less is unethical and terribly risky in today's trading environment. S. 746 would convert the current black box approach to one that is transparent.

S. 746 institutionalizes three widely accepted tools for risk managers including governments. These are cost-benefit analysis, risk assessment, and peer review. My area of experience is in public health regulation. Cost-benefit analysis would not normally be applied to public health measures because no cost can ethically be affixed to human health, suffering and death. Risk assessment on the other hand has become the universal language of scientific and public health deliberation. And peer review is the surety bond of science.

Risk assessment may be briefly described as the process of threat identification coupled with likelihood estimation with the end result being risk determination. For example, pasteurization of cheese is thought by some to be commercially objectionable but when the threat of cheese borne disease is

identified and the likelihood of that disease is calculated the risk associated with not pasteurizing is generally found to be unacceptably high.

I was privileged to have been invited to be a member of the Expert Consultation on Risk Assessment in Food Safety by the World Health Organization in Geneva from March 15-19, 1999. Among the conclusions of our Consultation was that all nations must implement risk assessment in their public health procedures at the earliest instance. This was because risk assessment is state-of-the-art in regulatory decision-making. The opposite of risk assessment is intuitive decision-making which may be based on either whimsy or politics or both.

I would now like to turn to peer review. This is the scientific equivalent of the old adage, "two heads are better than one." Its practical application comes when a panel of qualified individuals evaluate scientific papers, research projects, or the like. When used in the government, peer review has been successful. FDA's system of Generally Recognized as Safe (GRAS) is a form of peer review. This grew out of the 1958 Food Additives Act. GRAS affirmation generally means that if you can empanel a group of qualified individuals and they as a group attest that a substance is safe for the intended use at the recommended level, then FDA can consider it safe. The product specific advisory committees in FDA's Center for Drug Evaluation and Research constitute another useful example of peer review.

Peer review can and does broaden the expertise available to the government and it makes the process more open and democratic. In my personal and professional experience, OIRA could very much benefit from peer review.

Finally, let me address some of the criticisms that S. 746 has precipitated. The first is that the bill involves a "one size fits all" approach. This is wrong. S. 746 allows for exemptions for significant public health and other regulatory measures in the national interest. S. 746 also categorizes certain measures on the basis of the perceived impact on the economy. Therefore, it does not represent a one size fits all approach.

Much also has been made of the exemption from the Federal Advisory Committee Act (FACA) (section 625, page 24). While I have been and continue to be subject to that Act in my advisory committee and Special Government Employee roles and was charged to enforce the Act while at FDA and USDA, I think much can be learned from the National Academy of Sciences'(NAS) anguished decision to seek exemption from FACA last year. That effort resulted in Congress deciding to grant the exemption because it was persuaded that FACA requirements impeded peer review by intruding in a deleterious way on the deliberations of NAS committees. It is one thing to provide a transparent record of the conclusions of a committee and quite another to subject committee members to interruptions from non-committee members including the press during the deliberative process. FDA, when it approves a product provides to the public what is called a Freedom of Information Summary. These are transparent descriptions of the scientific basis upon which the approval is being made and are not in any sense a transcript of the deliberations. Even without FACA committee members have a legal and moral duty to recuse themselves from issues that stand to directly and/or financially benefit them.

The last point being made by opponents of S. 746 is that the bill "lowers the bar" on OMB-OIRA accountability. I cannot agree. The OMB that I was used to dealing with was buffeted from all sides by lobby groups of all kinds pressing subjective solutions to regulations of all types. And OIRA, being bereft of scientific expertise, overworked to the point of exhaustion, and increasingly unsure about what was best for America discovered new devices on a regular basis to delay or pigeonhole desperately needed regulations. I cannot tell you how many times I had to explain to OIRA that even deregulation requires a regulatory process that required their approval.

S. 746 will lead to better, more efficient government. I am convinced the bill provides a framework wherein regulatory initiatives can be fairly and openly judged in a transparent manner. My conclusion is that the bill will institutionalize risk assessment as the calculus for regulatory decision-making. To the extent that this is the case, S. 746 will bring the US in congruence with its international trading partners and the long-sought goal of science-based decision-making will at last have been realized.

Once again, thank you for inviting me to testify. I would be pleased to respond to questions.

TESTIMONY OF JOHN D. GRAHAM, Ph.D.

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April 21, 1999

Regulatory Improvement Act of 1999 (S. 746)
Committee on Governmental Affairs
United States Senate

My name is John D. Graham. I am Professor of Policy and Decision Sciences at the Harvard School of Public Health where I teach graduate courses in the methods of risk assessment, cost-effectiveness analysis, and cost-benefit analysis. I am also the founding Director of the Harvard Center for Risk Analysis (HCRA), an interdisciplinary unit dedicated to promoting a more reasoned public response to health, safety, and environmental hazards. In 1996 I served as elected President of the international Society for Risk Analysis (SRA), a membership organization of 2,500 scientists and engineers dedicated to promoting the methods and applications of risk analysis. The viewpoints expressed in this testimony should be attributed to me because they may not represent the official positions of my University, HCRA or SRA.

A brief biographical sketch may serve to highlight my interest in improving the regulatory process. I earned my BA and MA degrees in public policy from Wake Forest University (1978) and Duke University (1980), respectively. My Ph.D. dissertation at Carnegie-Mellon University (1983) was a benefit-cost analysis of automobile airbag technology and was conducted while in residence at the Brookings Institution in Washington, DC[1]. My airbag-related research was cited by the U.S. Supreme Court in the 1983 STATE FARM case against the Reagan Administration and by Secretary of Transportation Elizabeth Dole in her reinstatement of the airbag regulation in 1984. As a post-doctoral fellow in environmental health at the Harvard School of Public Health (1984-85), I investigated reform of air toxics regulation under the Clean Air Act in research published in the DUKE LAW JOURNAL. Based on this research, I later collaborated with Senator Daniel Patrick Moynihan (D-NY) on several features of the 1990 amendments to the

1 Graham, John D. Automobile Crash Protection: An Investigation of Occupant-Protection Policies. Ph.D. Dissertation, Carnegie-Mellon University: Pittsburgh, PA 1983.

Clean Air Act. In the 103rd Congress I worked closely with Senator Bennett Johnston (D-LA) on a risk-based amendment to the EPA Cabinet-elevation bill which passed the Senate but not the House. In the fall of 1994 I was commissioned by the American Enterprise Institute to write a blueprint for regulatory reform legislation[2]. This paper influenced the regulatory legislation (HR 1022) passed by the House of Representatives in March of 1995. In the 104th Congress, I also worked closely with Senator Dirk Kempthorne (R-ID) on risk-based amendments to the Safe Drinking Water Act and with Senators Robert Dole (R-KS) and Bennett Johnston (D-LA) on their comprehensive regulatory reform bill (S. 343). In the 105th Congress I was proud to work closely with Senators Fred Thompson (R-TN) and Carl Levin (D-MI) on S. 981, the precursor to the bill under consideration today.

For the past fifteen years, I have studied the decision making of federal agencies responsible for protecting public health, safety, and the environment[3]. These agencies include, for example, the Consumer Product Safety Commission, the Environmental Protection Agency, the Food and Drug Administration, the National Highway Traffic Safety Administration, the Occupational Safety and Health Administration, and the Nuclear Regulatory Commission. Although each of these agencies serve a vital public function, I have found that the decisions of these agencies are not always based on a good understanding of science, engineering, and economics. As a result, our regulatory system is far less effective and efficient than it could and

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2 Graham, John D. "Making Sense of Risk: An Agenda for Congress." Hahn, R. W. (Editor), Risks, Costs, and Lives Saved: Getting Better Results from Regulation (pp. 183-207). Oxford University Press: Oxford and New York, 1996.

3 Graham, John D., Green, L., and Roberts, M. In Search of Safety: Chemicals and Cancer Risk. Harvard University Press: Cambridge, MA 1990. Graham, John D. (editor) Harnessing Science for Environmental Regulation. Praeger: Westport, CT 1991. Graham, John D., and Hartwell, J.K. (editors) The Greening of Industry: A Risk Management Approach. Harvard University Press: Cambridge, MA 1997.

should be. One of my previous doctoral students at HCRA, Professor Tammy Tengs of the University of California at Irvine, found in her doctoral dissertation that lifesaving investments in the United States are often inefficient. Based on a sample of 200 policies, she estimated that a reallocation of lifesaving resources to cost-effective programs could save 60,000 more lives per year than we are currently saving, at no increased cost to taxpayers or the private sector[4]! In short, a smarter regulatory system can provide the public with more protection against hazards at less cost than we are achieving today.

Please let me cite three concrete examples of this regulatory inefficiency, cases where flawed regulatory decisions resulted from inadequate regulatory analysis.

1. THE RISKS OF "CLEANER" GASOLINE (MTBE)

In the 1990 amendments to the Clean Air Act, Congress sought to reduce carbon monoxide pollution in city air by ordering EPA to force an increase in the oxygenated content of gasoline. EPA later issued a rule that permitted a particular chemical, MTBE, to be used in compliance with the oxygenated fuel mandate. However, EPA never conducted a careful, quantitative analysis of the risks and benefits of MTBE compared to the alternative oxygenated fuels. Instead EPA allowed politics and market forces to shape implementation of the Clean Air Act, without any real understanding of the resulting risks and benefits to public health and the environment. Now that MTBE is widely used in gasoline in cities throughout the United States, serious questions are being raised about the safety and toxicity of MTBE. There are also reports that MTBE, a highly

4 Tengs, T. O., and Graham, John D. "The Opportunity Costs of Haphazard Social Investments in Life-Saving." In: Hahn, R. W. (Editor), Risks, Costs, and Lives Saved: Getting Better Results from Regulation. Oxford University Press: Oxford and New York, 1996. Tengs TO, Adams ME, Pliskin JS, Safran DG, Siegel JE, Weinstein MC & Graham JD. "Five-Hundred Life-Saving Interventions and Their Cost-Effectiveness". *Risk Analysis*, 15(3), 369-389, 1995.

persistent chemical, is contaminating groundwater supplies in several regions of the country. Not surprisingly, political opposition to MTBE is rapidly increasing throughout the country and thus EPA is scrambling around to find evidence in support of the oxygenated fuel requirement. EPA Administrator Carol Browner recently kicked this "hot potato" to an independent commission chaired by Dan Greenbaum of the Health Effects Institute. Such independent review is helpful. Yet what is missing today is the same thing that was missing in 1990: a careful risk-benefit analysis of MTBE and its alternatives. To make matters worse, it may be that the necessary scientific data to assess the risks and benefits of widespread use of MTBE in the fuel supply was never assembled by EPA or the private sector, making an authoritative risk-benefit study impossible.

2. MANDATORY FUEL ECONOMY STANDARDS FOR MOTOR VEHICLES

During the oil crisis of the mid-1970s, Congress responded by creating the Corporate Average Fuel Economy (CAFE) program. A federal agency, NHTSA, was charged with regulating the average fuel economy of the new vehicle fleets produced by each domestic and foreign vehicle manufacturer. Tougher standards were established for passenger cars than for light trucks. In the early years of the CAFE program, domestic vehicle manufacturers responded with some new technologies but they also made passenger cars smaller and lighter. As a result, cars have become somewhat more fuel efficient, but they have also became less safe than they would have been otherwise -- causing an additional 2,000 to 3,000 traffic fatalities each year due to the inferior occupant-crash protection provided by smaller vehicles[5]. More recently, the objectives of the

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5 Crandall, R., and Graham, John D. "The Effect of Fuel Economy Standards on Automobile Safety." Journal of Law and Economics, 32: 97-118 (1989). Graham, John D. "The Safety Risks of Proposed Fuel Economy Legislation." Risk: Issues in Health and Safety, 3: 95-126 (1992).

CAFE program have been circumvented by the growing popularity of sport-utility vehicles, a class of vehicles that has yet to be seriously analyzed for its safety and environmental consequences. To the best of my knowledge, the relevant federal agency, NHTSA, has never conducted a careful cost-benefit analysis of the CAFE program, even though they issue new rules under the program for each model year of vehicle production. The careful analyses of the CAFE program in the peer-reviewed scientific literature suggest that the entire CAFE program needs to be reconsidered, with greater attention to safety considerations and to the need for consumer incentives to purchase fuel-efficient vehicles.

3. PASSENGER AIRBAGS AND CHILDREN

When airbags and other automatic restraints were mandated in 1977 and again in 1984, concerns were raised that the passenger airbag might be dangerous to children seated in the front seat. Technical papers by engineers from General Motors Corporation and Honda Motor Company had already quantified the potential dangers of airbags to children. The relevant federal agency, NHTSA, did perform in 1980, and again in 1984, a (non-quantitative) risk assessment of airbags, with special attention to the safety of children. In these assessments, which was never subjected to independent peer review, NHTSA analysts concluded that the passenger airbag could endanger children under rare circumstances but the problem was unlikely to be widespread and serious. Moreover, NHTSA concluded (optimistically) that the number of children saved by airbags would far outweigh the number of children who might be killed or injured by the device. To the agency's credit, NHTSA published a real-world analysis in 1996 that showed how wrong the

1980 predictions were. Passenger airbags are causing a net increase in fatality risk to children under the age of ten, variously estimated as a net 20% to 100% increase in risk to children[6]. Consequently, NHTSA has belatedly joined the private sector in a massive campaign to encourage children to sit in the rear seats of vehicles with proper safety restraints. Given the technical concerns that were being raised about passenger airbag safety in 1980, I seriously doubt that NHTSA's 1980 assessment would have survived independent peer review. NHTSA would have been forced to either revise its passenger airbag rule to better protect children or to accompany the rule with warnings to parents that kids must be seated in the rear seat with proper restraint. In this case, NHTSA designed a regulation that has harmed children unnecessarily because the underlying regulatory analysis was flawed and never subjected to independent peer review.

Looking back on these three examples, it must be noted that we have much more knowledge today than Congress and regulators had when these decisions were made. The benefits of hindsight are considerable. Nevertheless, it is my opinion that each of these regulatory decisions and subsequent actions by Congress might have been quite different if the agency had performed the kinds of analyses envisioned in S. 746.

I am indeed honored to offer my enthusiastic support for S. 746, "The Regulatory Improvement Act of 1999." This bill would take four important steps toward a smarter regulatory system.

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6 Graham JD, Goldie SJ, Segui-Gomez M, Thompson KM, Nelson TF, Glass R, Simpson A & Woerner LG. "Reducing Risk to Children in Vehicles with Passenger Airbags," Pediatrics, 102, 1998.

First, S. 746 requires agencies to support major rules with regulatory analysis that includes risk assessment, substitution risk analysis, cost-effectiveness analysis and cost-benefit analysis. Although agencies do employ these tools today, their use by agencies is sporadic and inconsistent. S. 746 would set in motion a process, led by OMB, aimed at bringing more rigor, transparency, and quality to regulatory analysis in the federal government. The analytic guidelines mandated by S. 746, both the general guidelines prepared by OMB and the agency-specific guidelines, will be a major step toward a more analytical regulatory system.

Second, S. 746 requires agencies to make a cost-benefit determination about each major rule. The regulator must determine whether the anticipated benefits of the rule justify its costs, or why the rule is being issued without such justification. The bill does not alter the decision criteria in existing regulatory statutes enacted by Congress. This is an important weakness of S.746 since it is the flawed mandates of Congress that are often the cause of inefficiency[7]! Yet the uniform informational requirement in S. 746 is useful. It will provide future Congresses with valuable information that can be used to refine specific regulatory statutes in the years ahead.

Third, S. 746 requires peer review of agency analyses by scientists, engineers, and economists who are independent of the agency or program responsible for the rule. Today, any scientist has an opportunity to participate in either formal or informal rulemakings but the best scientists are unlikely to participate unless they are invited by the federal government to serve on a

7 Sunstein, Cass. "Legislative Foreword: Congress, Constitutional Moments, and the Cost-Benefit State." Stanford Review of Law, 48(247): 247-309 (1996).

peer review panel or similar body. Some scientists currently serve as hired consultants to specific stakeholder groups but the testimony of stakeholder groups is not a substitute for independent, objective peer review. Agencies that are currently performing competent regulatory analysis have nothing to fear from independent peer review. Experience shows that peer review, although not error-free, is a constructive device to enhance the technical competence and credibility of regulatory agencies[8].

Finally, S. 746 authorizes an important national study of risk-based priorities in the federal government. The results of this study are to be used by agencies to focus resources on the most serious risks, in conjunction with related requirements in the Government Performance and Results Act. By setting more rational agency priorities and stimulating better use of science in agency risk assessments, S. 746 will cause agencies to achieve more protection of public health and the environment than is occurring under our fragmented and inefficient regulatory system.

In conclusion, I see S. 746 as a modest yet important step toward a regulatory system that is more rational and transparent than the system we have today. Our regulatory debates will become better informed while our regulatory decisions will become more effective and less costly. Please do not hesitate to contact me if you should desire advice about how to make S. 746 an even stronger and more significant piece of legislation. Thank you very much for the opportunity to testify today.

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8 Graham, John D. (editor) Harnessing Science for Environmental Regulation. Praeger: Westport, CT 1991. Jasanoff, Sheila. The Fifth Branch: Science Advisers as Policy Makers. Harvard University Press: London and Cambridge, MA 1990.

Testimony of the
National Environmental Trust

On

S. 746
The Regulatory Improvement Act of 1999

Before the
Senate Committee on Governmental Affairs

Patricia G. Kenworthy
April 21, 1999

Introduction and Summary

On behalf of the National Environmental Trust, I wish to thank Chairman Thompson, Ranking Member Lieberman and the other members of the committee for this opportunity to present our views about S. 746, the Regulatory Improvement Act of 1999. I have been with NET for two years, as Vice President for Government Affairs and Senior Attorney. Before joining NET, I worked for Monsanto Company as Director of Regulatory Affairs. NET has participated in the discussions and debate about regulatory reform since the early days of the 104th Congress. We are pleased to have this opportunity to participate in this hearing today.

We have studied S. 746 carefully, as we did similar proposed legislation offered in the last Congress, and have thought carefully about the consequences of this bill becoming law. We believe we understand concerns about the efficiency and effectiveness of the regulatory system and appreciate the good intentions that led to introduction of this legislation. A more efficient and effective regulatory process benefits all of us. We also think the system can and should operate much better. Nevertheless, we must respectfully disagree with those who believe that this legislation will result in improvements in regulatory decisions. To the contrary, it is our belief that this legislation will result in extensive delays in the time it takes for regulatory decisions to be made and will thus undermine federal agencies' ability to protect public health, worker safety and the environment.

The provisions of S. 746, and its predecessor bill, S. 981, have been the subject of lengthy and open debate which has served well to educate all interested parties about the meaning of the language in the bill. This debate has also given us the opportunity to consider the intended and unintended practical consequences of enacting this legislation. We are very respectful of that process, and we appreciate that the sponsors of S. 746 have listened carefully to all parties. Many of the administration's recommendations for changes from earlier versions of this bill have been incorporated in S. 746.

Despite this, we believe the effect of this legislation will be to seriously undermine the operation of the regulatory system. Therefore, we must continue to oppose this bill.

It is our view that the ultimate test of comprehensive reform legislation, laid out in the letter from the administration to the chair of this committee dated March 6, 1998, has not been met. That test, as stated in Mr. Franklin Raines' letter to Chairman Thompson, is that such legislation "truly improves the regulatory system, and does not impair – by creating more litigation, more red tape, and more delay – the agencies' ability to do their jobs."

We believe that this legislation will greatly increase the time required for agencies to make regulatory decisions by imposing new responsibilities on already overburdened federal agencies. No provision is made for a corresponding increase in resources to address these newly imposed burdens. In some circumstances this legislation would subject new rules to inappropriate analysis which was never intended by the authorizing statutes. We also believe that provisions for peer review are unfair and have the potential to create the opportunity for the regulated community to unduly influence the decision making process.

Increased Delay

S. 746 requires new and difficult analyses be added to the decisonmaking process.

First, while agencies now engage in cost and benefit calculations and assessments in the rule making process, S. 746 imposes additional

requirements. Agencies must evaluate the quantifiable and nonquantifiable costs of any new rule covered by the proposed legislation. Evaluation of costs and benefits of nonquantifiable elements in some circumstances is not very easy to carry out. We discuss below an example in which an agency might be required to evaluate the benefit of the public's right to know and compare that to the costs associated with certain reporting requirements. Determining how to make these very subjective evaluations in ways which will withstand legal or political scrutiny is very likely to add significant time to the process.

Agencies are also required to evaluate the benefits and costs of "a reasonable number of reasonable alternatives reflecting the range of regulatory options that would achieve the objective of the statute as addressed by the rule making..." Sec. 623(b)(2)(A)(iv). The determination of a "reasonable number" and what is a "reasonable alternative" will be difficult and time consuming. Agencies will be petitioned by interests on every side of an issue to consider alternatives they believe to be appropriate and which in many cases will be very controversial.

In addition, agencies are required to perform two risk assessments, one at the earliest stage in the rule making process and the second when the final rule is issued. While the bill technically gives the agency the ability to waive the second risk assessment, we believe agencies will be reluctant to do this out of concern for challenges to the final rule. Even if the agency does only one risk assessment, as technically permitted by S. 746, this is still a new mandate beyond the currently effective executive order. It will add time to the rule making process and will require additional resources. Furthermore, as discussed in more detail below, this provision in S. 746 may actually require risk assessments even in cases where a risk assessment cannot possibly be performed.

Another new requirement imposed by S. 746 is to conduct peer review of all major rules and of certain cost-benefit analyses. The issues raised by this new requirement are also discussed in more detail below. It can be noted here that peer review is never a simple process and there is no doubt this requirement increases the effort and time required for promulgation of new rules.

These are major new requirements imposed on already over-burdened agencies. It is our strongly held view that these new requirements should

not be imposed at all, but certainly not without providing for sufficient additional resources to make it possible for the agencies to meet these new demands. Today, without these additional requirements, it often takes OSHA and EPA more than ten years to enact major new worker safety and environmental standards. Imposing new requirements without new resources will necessarily increase this already scandalous timeframe for enacting new regulations to protect human health, worker safety and the environment.

New Analyses Which May Not Conform to the Intent of the Authorizing Statute

Many examples could be cited as potential conflicts with the intent and purposes of other statutes if S. 746 were enacted. We will describe only two here.

Consider the Clean Air Act Maximum Available Control Technology (MACT) standards. For decades, EPA struggled with attempting to issue new clean air regulations based on risk assessments in accordance with the Clean Air Act as enacted by Congress. Because of a lack of necessary data (which is not the same thing as the absence of authoritative and responsible assessments of danger to human health and the environment) most risk assessments could not be completed. New and much needed clean air regulations were not issued. The Congress then amended the Clean Air Act to change the standard for issuing new regulations from risk to an evaluation of available technology. Once this was done, new regulations began to be promulgated and the air is now much cleaner, people and the environment are better protected. Is S. 746 to be read as now requiring that EPA go back to performing risk assessments on clean air regulations promulgated under the technology standard? This certainly would be inconsistent with Congress' intent when it created the MACT standard in the Clean Air Act amendments. More importantly, it would recreate the problem the MACT standard was designed to correct and result in the agency once again finding it impossible to issue new protective standards.

This example points up another important issue with respect to these new requirements. The statute requires that agencies estimate a rule's benefits by means of a risk assessment. If data are inadequate to perform a risk assessment, as they are in numerous circumstances, how are benefits to be calculated consistent with this new requirement? It is not appropriate to

argue that if there are inadequate data to complete a risk assessment, there is no basis for regulation. Data needed to complete a quantitative statistical risk assessment are not the same as data needed to make a valid determination that a risk exists and must be controlled or eliminated, at least until such time as more information is known about the risk.

Preventing regulation absent sufficient data to complete a quantitative risk analysis undermines precautionary approaches. Suppose we see a river becoming very polluted because of chemical discharges, but don't yet have enough data to determine the quantitative statistical risk associated with a certain contaminant in a community's drinking water. We would not want to be precluded from acting to protect the river and the drinking water until a risk assessment could be completed.

Another example which points out the potential for conflict between the requirements of S. 746 and existing laws is the Toxic Release Inventory reporting law (Emergency Planning and Community Right to Know Act). This law requires that industry report (not control) the levels of certain chemicals emitted from a facility. It was enacted in the shadow of the Bhopal, India accident, which killed and seriously injured many thousands of people. One of the purposes of the statute is to provide communities around chemical manufacturing facilities with information about what toxic substances are being emitted from these facilities. There is no requirement under this statute that exposure data be collected. TRI is not a risk-based statute. It is a community right-to-know law.

Would S. 746 require EPA to do a cost-benefit analysis before adding a new chemical to the inventory of chemicals that must be reported? Would EPA be required to perform a risk assessment to determine benefits for the cost-benefit analysis before such a rule could be issued? How is it possible to do a risk assessment on making information available to the public? How does one measure the benefits of the public's right-to-know, and compare that virtually unquantifiable benefit to the cost industry will incur in complying with the reporting requirements? What standards would a peer review panel apply to evaluate this cost-benefit analysis? The answers to these questions all come down to this: there is no way to apply principles of risk assessment and cost-benefit analysis to principles of democracy such as community right to know laws.

One benefit of the right-to-know law has been that industry has voluntarily reduced the amounts of emissions of toxic chemicals in order to avoid the reporting requirement. How can this benefit be predicted with any precision since it is voluntary, let alone evaluated sufficiently to stand as part of the cost-benefit analysis? How does the agency adequately calculate the value of reducing the emission of some toxic, high-volume chemical about which there is not enough known to perform a risk assessment?

These examples are meant to demonstrate the difficulties and potential for unintended consequences when an attempt is made to reform perceived problems in the regulatory system with a single comprehensive piece of legislation. A single new set of rules will not operate effectively to make rational and productive improvement in a system this complex. If there are problems in need of resolution, the individual laws from which these problems arise should be addressed and appropriate solutions found.

The Congress has recently enacted excellent regulatory reform legislation that is crafted to effectively improve the outcome of regulatory decision making. These recently enacted new laws include amendments to the Safe Drinking Water Act and the Food Quality Protection Act, which amended the Federal Insecticide, Fungicide and Rodenticide Act and the Food, Drug and Cosmetic Act. In these statutes, the regulatory reform provisions were designed to specifically address the areas in those particular statutes that needed to be changed. The Congress thus avoided the problems that are inevitable in comprehensive legislation such as S. 746.

Peer Review

The Regulatory Improvement Act of 1999 requires that agencies provide for independent peer review of certain cost-benefit analyses and all risk assessments required under the act. Peer review is, of course, an accepted and respected process for helping to guarantee the scientific basis and adequacy for regulatory decisions, and is used by many federal agencies routinely. The benefits of a peer review process are easily overcome, however, if the process is structured in a way that creates inequities.

In the case of the process created by S. 746, there is a specific requirement that reviewers must be "independent of the agency" (Sec. 625 (b) (A) (ii)). This provision reaches much further than excluding people in the program office responsible for writing the rule. It would exclude experts who have

no connection with the rule making decision. Qualified scientists (and economists, in the case of cost-benefit reviews) are not so plentiful that there is no hardship resulting from excluding them arbitrarily. On the other hand, there is no prohibition in the bill against peer reviewers who are affiliated with industry and are not independent of the financial implications of the outcome of the decision. Neither kind of conflict of interest should be permitted. To be fair, the bill should limit the exclusion of government experts to those that may actually have a stake in the outcome of the decision and should clearly prohibit people with a financial interest.

We also have a very practical concern about the operation of the cost-benefit peer review process set out in S. 746. Much of EPA's information used for the cost side analysis of cost-benefit evaluations comes to EPA from industry. We have seen time and time again that industry consistently overestimates regulatory costs (Goodstein and Hodges, "Polluted Data: Overestimating Environmental Costs, The American Prospect, Nov-Dec, 1997, copy attached). EPA, aware of the history of industry overestimating costs, may modify some of the industry numbers. Since there is no conflict of interest prohibition for persons affiliated with industry, it can be foreseen that there will be reviewers on a panel who are sympathetic to and will defend industry's cost estimates. If EPA sticks to its decision despite criticism by these reviewers, the criticism, but not necessarily the potential bias of the reviewer, is in the public record. This record is subject to legal and political review. Such a system creates the opportunity for unfair influence.

Yet another concern we have with the peer review process in S. 746 is the requirement that peer reviews be conducted on cost-benefit evaluations. Rarely, if ever, has a peer review been performed by an agency on a cost-benefit analysis. The Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget usually performs this sort of review. The extra step of a separate peer review of cost-benefit evaluations is unnecessary. It is quite likely that these reviews will often be complex and will add many months to the rule making process only to duplicate the OIRA review.

We are also concerned about the provision that exempts the peer review process from the Federal Advisory Committee Act (FACA) requirements for public access. These reviews should be open to some form of public participation and scrutiny, particularly if there is nothing in the law to

prevent peer review panels from including people with industry affiliations and financial interest in the outcome of the rule making process. For many years, the EPA Science Advisory Board and FIFRA Science Advisory Panel review processes have been open to public observation, and this has caused no serious impediment to the operation of either of these review procedures.

Another problem with the process defined by S. 746 is the "balance" requirement. The bill requires that the review "contain a balanced presentation of all considerations, including minority reports and an agency response to all significant peer review comments." (Sec. 625 (b)(1)(D)) This raises the very real possibility that a single reviewer, whose views are well outside the consensus of other responsible and respected experts, could be given equal weight with opinions reflecting scientific consensus. Fair representation is essential to a fair process. However, including any and every view under the justification of "balance" opens up the opportunity for the unscrupulous to manipulate and undermine the process.

The peer review provisions create redundancies and impose enormous new burdens on the agencies without corresponding provision for additional resources. The process is structured in a way to create the potential to operate unfairly and is subject to manipulation by the regulated community.

OMB Review Process

S. 746 contains provisions that would allow the Office of Management and Budget to take an unlimited period of time to review proposed rules, thus delaying the promulgation of the final rule indefinitely. We have had experience with prior administrations subjecting regulations to review for indefinite periods. We called this the regulatory "Bermuda triangle" into which new rules just disappeared. We certainly object to seeing a return to that sort of practice.

Conclusion

During the past few years, the Congress has enacted a number of new laws to address problems and shortcomings in the existing regulatory process. These include the Small Business Regulatory Enforcement Fairness Act of 1996, the Unfunded Mandates Reform Act of 1995, regulatory accounting requirements attached to appropriations bills and the Paperwork Reduction Act of 1995. It may be that these new laws will serve to address and correct

perceived problems. We don't have enough experience with them yet to know for sure. Before enacting far reaching comprehensive legislation, we should allow more time to judge the effectiveness of these new statutes and determine what real problems remain and how they might best be addressed.

This comprehensive legislation attempts to address perceived problems arising from an array of many different statutes that have diverse purposes and goals. These many affected statutes are administered by many different federal agencies with distinct missions. We don't think this kind of comprehensive legislation can possibly effect improvements under those circumstances. We believe that it will instead do great harm to protection of human health, worker safety and the environment. We oppose this legislation and hope this committee will determine it should not be enacted.

This concludes my statement. I am pleased to answer any questions.

EBAN GOODSTEIN AND HART HODGES

Polluted Data: Overestimating Environmental Costs

In July, Carol Browner, chief of the Environmental Protection Agency, issued new regulations reducing permissible levels of smog and particulate (fine soot) pollution. The political battle leading up to the decision was fierce, even within the administration. One staff member on the Council of Economic Advisers maintained that the regulations would cost a whopping $60 billion—a figure quickly seized upon by industry opposition. The EPA's own cost estimate was much more modest, between $6 billion and $8 billion. In making her case for the new regulations, however, Browner publicly disavowed even her own agency's cost estimates. She argued that industry would find a way to do it cheaper.

Whom to believe? Confronted with conflicting estimates, most lay people either throw up their hands or choose sides ideologically. But history provides a basis for evaluating these estimates. Not only do industry lobbyists wildly overestimate the costs of proposed environmental regulations. More surprisingly, academic and government economists consistently do too—and for an equally surprising reason. When forecasting the costs of new environmental regulations, economic analysts routinely ignore a primary economic lesson: Markets cut costs through innovation. And innovation can be promoted through regulation. This history is worth bearing in mind as we approach the most important environmental controversy to date—how to deal with the crisis of global warming.

THE ABCS OF OVERESTIMATION

In every case we have found where researchers have calculated actual regulatory costs and then compared them to *ex ante* estimates, the estimate exceeded the actual cost. We have uncovered a dozen such efforts, ranging from A (asbestos) to V (vinyl chloride). In all cases but one, the initial estimates were at least double the actual costs.

Asbestos. When the Occupational Safety and Health Administration (OSHA) instituted regulations covering exposure to asbestos in the early 1970s, they hired a consulting firm to estimate the cost of compliance. Two later studies found that the original prediction for the cost of compliance was more than double the actual cost, because of overly static assumptions.

Benzene. In the late 1970s, the chemical industry predicted that controlling benzene emissions would cost $350,000 per plant. Shortly after these predictions were made, however, the plants developed a process that substituted other chemicals for benzene and virtually eliminated control costs.

Chlorofluorocarbons (CFCs). In 1988, reducing CFC production by 50 percent within 10 years was estimated by the EPA to cost $3.55 per kilogram. By 1993, the goal had become much more ambitious: complete elimination of CFC production, with the deadline moved up two years, to 1996. Nevertheless, the estimated cost of compliance fell more than 30 percent, to $2.45 per kilogram. And where substitutes for certain CFCs had not been expected to be available for eight or nine years, industry was able to identify and adopt substitutes in as little as two years.

CFCs in automobile air conditioners. In 1993 car manufacturers estimated that the price of a new car would increase by $650 to $1,200 due to new regulations limiting the use of CFCs. In 1997 the actual cost was estimated to be $40 to $400 per car.

Coke ovens. The original OSHA estimate for the cost of complying with the 1976 coke

oven standard was more than five times higher than estimates of actual costs. OSHA's contractor suggested that complying with the standard would cost from $200 million to more than $1 billion. However, a Council on Wage-Price Stability study later estimated the actual cost of the standard to be $160 million.

The OSHA consultant estimated that three steel firms in their sample would spend $93 million on capital equipment and $34 million in annual operating costs to comply with the regulations. A later study by Arthur Andersen determined that the three firms actually spent between $5 million and $7 million in 1977 to comply with the standard, and only $1 million to $2 million on capital expenditures. Ultimately, firms were able to meet the standard without incurring all of the capital costs in the first year, and actual compliance costs were dramatically lower than originally predicted.

In the late 1980s, coke production again came under regulatory scrutiny, this time by the EPA. In 1987, the agency estimated that the cost of controlling hazardous air pollution from coke ovens would be roughly $4 billion. By 1991 that estimate fell to between $250 million and $400 million.

Cotton dust. In 1976, OSHA proposed a maximum permissible exposure limit of 0.2 milligrams per cubic meter for cotton dust, and its consultant estimated that compliance costs would be approximately $700 million per year. The standard promulgated in 1978 actually allowed for higher exposure levels in some sectors of the textile industry, but the small changes in the standard do not fully explain the decrease in estimated compliance costs; in 1978 the estimate fell to $205 million per year. Moreover, a new study conducted in 1982, after the Reagan administration called for a review of the standard, concluded that compliance costs were $83 million per year.

Halons. In 1989 members of the United Nations Environment Program's Halons Technical Options Committee disagreed on whether direct halon replacements could be found and whether a phase-out was possible. However, in 1993 the committee concluded that a phase-out of halons, a substance found in fire extinguishers that destroys the ozone layer faster than chlorofluorocarbons, would be both technologically and economically feasible by 1994.

Strip mining. Prior to the passage of the 1978 Surface Mining Control and Reclamation Act, estimates for compliance costs ranged from $6 to $12 per ton of coal. Actual costs for eastern coal operations have been in the range of 50 cents to $1 per ton. After the regulations were adopted, the market switched away from coal deposits with high reclamation costs. Ready substitutes included surface-minable coal in flatter areas (with lower reclamation costs), and underground deposits.

Vinyl chloride. OSHA's vinyl chloride standard, set in 1974, provides a final example of wildly excessive cost projections. The agency's consultant estimated that it would cost $22 million per year to meet the permissible exposure limit of 2 to 5 parts per million (ppm) in the vinyl chloride monomer sector, and $87 million per year to meet the 10 to 15 ppm exposure limit in the polyvinyl chloride sector. In addition, the consultant argued that the 1 ppm permissible exposure limit simply could not be attained. The president of Firestone's plastics division said that a standard of 1 ppm "puts the vinyl plastics industry on a collision course with economic disaster."

In spite of these protests, OSHA did adopt the strict permissible exposure limit of 1 ppm. A study conducted several years later by researchers from the Wharton School of Business estimated that the total cost of compliance for *both* sectors had been about $20 million per year. A 1976 congressional research paper also indicated that the actual cost of compliance was dramatically less than the original prediction. The early claims that the 1 ppm standard could not be met evaporated; instead, the regulatory action led to about a 6 percent rise in polyvinyl chloride prices.

While costs have been consistently overestimated for emission reduction, they have been underestimated for environmental cleanup. For example, when the Clean Water Act was enacted in 1972, the EPA estimated that $12.6 billion was needed to provide secondary sewage treatment systems. According to the American Enterprise Institute, actual spending for sewage treatment between 1972 and 1981 exceeded $160 billion.

Costs for the Superfund program have also mushroomed. When first launched, people expected the mandated cleanups to apply to a small handful of Love Canals. However, the pro-

gram has expanded dramatically, now covering far more than a thousand sites. In addition, cleanup has proved far more costly than predicted: The average cost overrun on cleanup expenditures at Superfund sites has been 44 percent.

The message from these cases is clear. On the one hand, treating already polluted water, cleaning dirty soil, and scrubbing oily rocks costs a lot of money, (much) more than expected. On the other, when it comes to reducing pollution emissions at the source, it is almost certain to be (substantially) cheaper than we think it will be. Updating *Poor Richard's Almanack*, an ounce of prevention is clearly worth a pound of cleanup.

Why were the estimated costs of reducing emissions at the source so inflated? The reason, of course, is "technology-forcing." When industry is required to lower pollution output, it usually doesn't just slap a new filter on an existing process; it often invents new technology. Frequently the new technology turns out to have higher productivity benefits, which help to offset the cost of the regulation. To see this, it is worth looking in detail at two high-profile cases where markets have responded to regulation by cutting costs.

Coke Break

Robert Hahn, a well-known environmental economist, is currently a resident scholar at the American Enterprise Institute and an adjunct research fellow at Harvard's Kennedy School of Government, and is a former senior staff member of Bush's Council of Economic Advisers. In 1990 he and a co-author wrote a report for the U.S. Business Roundtable predicting the impact of the proposed Clean Air Act amendments on employment. These amendments had the dual purpose of cleaning up both acid rain and so-called "air toxics" from industrial plants.

The executive summary of Hahn's report leaves "no doubt that, across the Clean Air Act Amendments studied, there are a minimum of several hundred thousand jobs at various levels of severity of risk—even with the more moderate [Bush] Administration proposals." Hahn's absolute minimum prediction was 20,000 jobs directly lost, mostly from the closing of coke ovens in the steel industry. Hahn and his co-author viewed this as "truly a limiting, rock-bottom estimate" for several reasons. Important among them was that it considered only job losses arising from one portion of the bill—control of air toxics.

The amendments did pass later in 1990. The bill was in most respects more restrictive on air toxics than the one on which Hahn's study based its minimum job loss estimates. The legislation also authorized retraining funds of $50 million per year for displaced workers, which gives a nice way to track job impacts.

In the almost seven years since passage of the legislation, fewer than 7,000 workers have received aid because their jobs were affected by the Clean Air Act amendments. And the vast majority of these have been eastern, high-sulfur-coal miners, who have been laid off due not to the air toxics provision, but to the acid rain amendment. (The same legislation has in fact led to a boom in the western, low-sulfur-coal industry.) No workers from shutdown coke oven plants have received adjustment assistance. And between 1992 and 1995, production in the coke and (closely related) blast furnace industries actually increased, from $1.74 billion to $1.95 billion.

Hahn was consulting for industry here, so it is not surprising that his numbers were a bit on the high side. Corporate America, when faced with new regulations, has never been shy about claiming that the sky is falling. But Hahn is not a hired gun; he has very solid academic credentials. How could he have gotten it so wrong?

It turns out that Hahn's overestimation of regulatory impacts, while extreme, is not unusual. In fact, as we have seen in every case for which we have been able to track down data, academic and government economists have routinely overestimated the costs of reducing pollution emissions—by at least 30 percent, and generally by more than 100 percent.

The Acid Test

The EPA's acid rain program is another dramatic case in point. Since 1995, electrical utilities have been required to hold permits for each ton of sulfur dioxide they emit. These permits, in limited supply, are distributed to firms each year by the government. The innovative feature of the program is that the permits can then be bought and sold. Given this, permit prices roughly reflect per ton pollution control costs. This is true because a firm generally wouldn't buy an extra

permit if the cost of doing so exceeded the cost of reducing sulfur emissions by a ton.

When the tradable permits market was being designed in the early 1990s, credible industry estimates of permit prices (and thus control costs) were $1,500 per ton; the EPA was predicting $750. In 1997, permits were in fact selling for around $100 a piece.

Part of the current low permit price is due to a higher than expected initial supply of permits, but real compliance costs have in fact been two to four times lower than the EPA expected, and four to eight times below industry estimates.

The Virtue of Markets

When environmental economists figure their cost estimates, one particular lapse is quite startling. Economists have tended to grossly underestimate a virtue of markets they readily preach elsewhere: flexibility. When pollution regulation makes a certain type of production more expensive, markets adjust—in fairly rapid order, uncovering substitute methods of production, and developing cheaper cleanup technologies. This fact, while not completely ignored by economists, is seldom factored into their cost estimates. Instead analysts tend to predict future costs statically, as if firms would continue to use existing practices and technologies.

So, for example, the much lower than expected costs for the acid rain program can be explained in retrospect by the increased flexibility that firms were given to achieve their mandated reductions in sulfur dioxide emissions. Rather than install expensive scrubbers (or buy extra permits), many more firms than expected have met their sulfur dioxide targets by switching to low-sulfur coal, or developing new fuel-blending techniques. Railroad deregulation, along with economies of scale, led to an unexpected decline in low-sulfur-coal prices. And with the increased competition from coal, scrubber prices fell by half from 1990 to 1995.

All this is easy to see after the fact, but would have been very hard to predict. Hahn got his 20,000 lost jobs from air toxics regulation following this same practice—ignoring innovative market responses. While parenthetically noting that "technological improvements could reduce the direct economic impacts," the study explicitly ignores the possibility "because of the difficulties in predicting how technology will evolve." Because in the mid- to late 1980s, available control technologies for coke ovens seemed to be quite expensive, Hahn assumed that regulating air toxics would simply shut down much of the industry.

However, as we saw above, the EPA's own estimates of control costs for coke ovens were plummeting even as Hahn was writing his report. By 1991, they were down by a factor of ten or more from the 1987 forecasts. Hahn may not have been aware of the EPA's work; instead he cites an industry source to justify his claim that "there is widespread agreement that coke ovens will be required to close down, with an estimated loss of 15,000 jobs."

A secondary reason for the overestimates is that in implementation, legislation is never as draconian as it appears on paper. In practice, timetables get stretched out, compliance dates get extended, and waivers are granted. Eventually the regulations begin to bite, but industry is usually given a fair amount of time to adjust. Most cost estimates assume high degrees of near-term compliance.

Peering into the future is hard work. It is, in fact, close to impossible for economists to predict the specifics of how technology will evolve. This is especially true since much of the information about potential innovations consists of closely held trade secrets, which industry has little incentive to reveal. But basing cost predictions on scenarios that assume no technical evolution is guaranteed to produce gross overestimates. Innovation is indeed something at which markets are very good. When given a narrowly defined task—to produce commodity *x* emitting less of pollutant *y*—short-term substitutions and long-term shifts in technology guarantee large cost reductions over current practice.

Inflating Costs, Ignoring Benefits

In the late 1980s, when the international phase-out of ozone-destroying CFCs got underway, a company called Nortel began looking for substitutes. The company, which had used the chemicals as a cleaning agent, invested $1 million to purchase and employ new hardware. Once the redesigned system was in place, however, Nortel found that it actually saved $4 million in chemical waste-disposal costs and CFC purchases.

The CFC regulatory compliance costs for Nortel clearly were $1 million. But how do we figure in the $4 million savings? Economists have long recognized that a dollar spent on environmental pollution control is not the "true" cost to society. Some have argued that the cost is in fact much higher, because environmental spending "diverts" capital investment from more productive uses.

In recent years, by contrast, Michael Porter of the Harvard Business School has been pointing to examples like Nortel to argue that environmental regulations, by forcing firms to rethink their production processes, can often lead to lower production costs and lend a competitive advantage.

More generally, much of the reported costs of environmental regulation occurs when firms invest in new capital equipment, thoroughly redesigned to be both cleaner and more productive. Many of these investments would have happened sooner or later anyway. So a primary effect of regulation is to speed up the investment process. This is costly to firms, since they must scrap old machinery that is not necessarily worn out. When this happens, however, much of measured compliance cost is in fact just early capital investments. This in turn implies that the compliance figures are much higher than the real costs.

Researchers at Resources for the Future recently conducted a study asking how much $1 spent on environmental protection really costs an industry. For some industries, specifically steel, the answer was little more than $1, due to the diversion effect. For others, notably plastics, the industry actually saved money as productivity was boosted. On average, the study concluded, $1 spent on environmental pollution control reflected a real expense of 13 cents. In general then, even when cost estimates are "correct," this new research suggests that the reported values often overstate the true costs to the firm, on average by a factor of seven.

The Road to Kyoto

The debate over compliance costs is now heating up for the mother of all pollution issues—global warming. International negotiators are at work on what are supposed to be binding carbon emission reduction requirements, to be announced in Kyoto in December. The European Union is pushing for a 15 percent cut below 1990 levels to be achieved by 2010; the members of the Alliance of Small Island States—whose very existence is at stake due to anticipated flooding—want a 20 percent cutback by 2005.

The United States, by far the world's biggest greenhouse polluter, is dragging its heels. President Clinton, when pressed to commit the U.S. to specifics, has promised only to convene a conference in the fall to try to achieve a consensus among American industry, labor, and other groups on the need for action. And Clinton will clearly face a tough sales job for ratification in the Republican-controlled Senate.

Academic economists have lined up behind a strong U.S. leadership role in Kyoto. Greenhouse "moderates" like Yale's William Nordhaus and Harvard's Dale Jorgenson headed up a list of more than 2,000 economists who signed a letter arguing that a first round of carbon emission reductions could be achieved at relatively low cost. And in late July, to the dismay of U.S. industry, the Clinton economic team published its official cost estimates, confirming this general view.

There is a minority opinion among economists that reducing greenhouse gas emissions will be very, very cheap, and in the long run, even profitable. The reasons? Already existing energy efficiency technologies can help the United States break its addiction to cheap oil without too much pain. And within a decade or two, renewable fuel sources—coupled with efficiently redesigned technologies—will be cheaper than oil or coal are today. In this view, the sooner we redirect the market into a serious search for alternatives to fossil fuels, the richer we will be in the future.

There are, however, likely to be transitional costs, both for workers, particularly in fossil fuel industries, and for Third World countries. In the past, government has not done a very good job in equitably sharing the burdens of such transitions. This is no reason to reject a global warming accord, but it is a strong reason to be alert to the allocation of costs and benefits.

In the global warming debate, as when past environmental regulations have been proposed, there are the three compliance cost scenarios: apocalyptic (industry), doable but costly (academic and government), and profitable (a few visionaries). Our guess, based on the record of previous academic and government cost forecasts, is somewhere between doable and profitable.

TESTIMONY OF DR. FRANKLIN E. MIRER
DIRECTOR OF THE HEALTH AND SAFETY DEPARTMENT

on behalf of the

International Union, United Automobile, Aerospace, and Agricultural Implement Workers of America (UAW)

On The Subject Of

Regulatory Improvement Act of 1999 (S.746)

Before The

Committee on Governmental Affairs United States Senate

Washington, D.C. April 21, 1999

I am Dr. Franklin E. Mirer, Director of the Health and Safety Department of the UAW. I am a toxicologist and certified industrial hygienist. I speak today on behalf of nearly 1.3 million active and retired UAW members and their families.

The UAW strongly opposes the proposed "Regulatory Improvement Act of 1999" (S. 746). We appeared here a year ago to oppose the Regulatory Improvement Act of 1998, and for the same reasons. We believe this legislation imposes a "one-size fits all, one style suits all" procedural mandate which would undermine OSHA's ability to protect working men and women against workplace health and safety hazards.

Next week, the AFL-CIO, the UAW and other unions will observe Worker Memorial Day to remember victims of occupational injury and disease. The UAW and its local unions will fly flags at half mast and read the names of the six victims of the Ford Rouge Powerplant explosion, two other UAW members killed by work in 1999, and 11 victims in 1998. But the names of most victims of occupational hazards are unknown. Occupational disease is estimated to cause ten times as many deaths as occupational injury does and over 100,000 UAW members suffer an occupational injury or illness each year. UAW members are among the best protected of American workers, and yet we sustain these losses year after year.

Our members and their families will not tolerate an erosion of health and safety protections at work. Most of the fatalities recorded in our facilities, and virtually all of the occupational disease identified among our members by research, arose from conditions not covered, or exposures permitted by existing OSHA standards. Our members want Congress to expand and strengthen health and

safety protections by making it possible for OSHA to set more comprehensive and more protective standards.

The UAW opposes S. 746 because it contains not a single provision that would facilitate improving OSHA standards, or any other public health or consumer protections. From a worker perspective, the most significant problem with agency regulations is delay in responding to documented hazards. This bill does not pretend to cure the problem of delay. Instead, it makes the delays worse and erects further barriers to new health and safety rules for our members and for all American workers. Specifically, S. 746 would:

- add additional time consuming steps to the standard setting process;
- give industry representatives a special seat at the table and an inside track to oppose a new standard;
- provide many new grounds for industry to challenge standards in court;
- eat up OSHA resources with complex analyses irrelevant to the OSHA law;
- shift the balance in standard setting decisions from worker protection to industry costs.

The legislation tilts the playing field further in favor of those who wish to block new protections. Like all recent regulatory legislation, S. 746 seems based on the assumption that public health agencies order overly protective limits too fast and too frequently, based on extreme interpretations of science. Claims that the bill would add transparency and consistency to the public health process are incorrect. Real world experience suggests just the opposite.

The UAW urges this Committee to take into account actual experience with specific public health statutes before entangling them all in this single net of complex procedural requirements. The history of the metalworking fluids standard furnishes a real world example of the current obstacles at OSHA and the ways in which the requirements proposed in S. 746 would adversely affect OSHA standard setting procedures.

About a million American workers are exposed to metalworking fluids in factories that make engines, transmissions, bearings and many other machined products. The National Institute for Occupational Safety and Health (NIOSH) has concluded that these materials pose respiratory, skin and possibly cancer hazards under current conditions of use. UAW efforts to protect our members from these dangerous materials started with two cancer studies in bearing plants in New Britain, and Bristol, Connecticut in the early 1980's. These studies found increased cancer due to exposures that were within or not covered by OSHA limits. Since then, the UAW and the auto manufacturers have conducted several million dollars worth of jointly directed research into cancer, respiratory effects, toxicology and control technology for metalworking fluids. We have

demonstrated respiratory illness not previously found in the scientific literature. We have shown that the standard ventilation systems actually increased some exposures.

The respiratory effects of metalworking fluid exposures can be devastating. And yet there is not, to date, an OSHA standard adequate to protect workers. Consider the situation of UAW Local 72 members at Chrysler's Kenosha, Wisconsin Engine Plant. In August of 1995, the first employees at this facility developed hypersensitivity pneumonitis (HP), a rare, severe condition of the deep lung. HP presents with fever, chills, shortness of breath and loss of weight. With recurrences, acute HP may become chronic HP, resulting in lung scarring, progressive loss of breath and even death. The UAW and Chrysler were aware that no exposure in the facility remotely approached OSHA's Permissible Exposure Limit for oil mist, and that OSHA required no medical examinations or tests for employees with such exposures. Nevertheless, Chrysler took vigorous joint action in cooperation with the UAW to respond to this problem.

The UAW and Chrysler together called in the Wisconsin Division of Health in March of 1996 and provided funding to the government agency to conduct an investigation. By September 1996, the study had identified 20 employees with HP and nearly 40 others with other significant respiratory conditions. According to our local union representatives, a significant number of these HP victims are unable to return to work, even under dramatically improved conditions. They are suffering the devastating psychological as well as physical consequences of an occupational illness.

The UAW and Chrysler could not sit back to wait for OSHA or for more research. When the HP risk was identified, ventilation in the plant was immediately improved. The facility was designated a pilot plant for best control technology in the 1996 collective bargaining agreement. Enclosures and local exhaust ventilation were installed on existing and new equipment and truly remarkable reductions of exposure were achieved. No new HP cases have appeared since 1997, and other respiratory complaints are down drastically.

With more time, we could have brought victims, local union representatives and management representatives to today's hearing to tell the whole story. It would take a day to do the story justice.

UAW, Chrysler and NIOSH sponsored a national workshop on HP and metalworking fluids at the UAW-Chrysler National Training Center in Detroit in January 1997. The workshop examined similar outbreaks of metalworking fluids-related respiratory illness in UAW eight represented facilities in the US and Canada. Since then, at least four other outbreaks have been identified. Proceedings of the workshop, as well as research papers from the investigation, were published in scientific journals

Where has OSHA been during all of this? OSHA did not react to the cancer studies published in the middle 1980's or to the respiratory effects studies. The UAW petitioned OSHA for a new standard for metalworking fluids in November 1993. After four years, OSHA finally put together a Standards Advisory Committee of health professionals and representatives of labor, management and state agencies, on which I serve. We have met eight or nine times, visited plants, heard from victims and considered testimony of experts. NIOSH issued a criteria document that warned of respiratory, dermatitis and possible cancer effects, and recommended an exposure limit one tenth of the current OSHA standard. NIOSH also has visited about 80 plants to assess the feasibility of the proposed new limit. The Advisory Committee is trying to complete a final report and recommendation before our charter expires.

The bad news is that OSHA has yet to summarize the known health effects, carry out the existing requirements for an economic feasibility analysis, or draft and justify regulatory text. I would estimate at least a year's work for that, after the Advisory Committee completes its task. Then there is the review required under the Small Business Regulatory Enforcement Fairness Act (SBREFA), the OMB review and who knows what other review! And that's all before OSHA can issue a proposal and hold the public hearing. After the public hearing, the record has to be summarized and a whole new round of reviews must take place before a final standard can issue. After that, Congress has the opportunity to "veto" the rule through Congressional disapproval or, failing that, an appropriations rider. That is a real life example of the present situation.

Now, if S. 746 were to become law, even if the Metalworking Fluids Advisory Committee members were to reach complete agreement about every issue in the standard, OSHA would still have to conduct a new formal risk assessment, a different cost benefit analysis, a substitution risk analysis and a comparative risk analysis. Then OSHA would be subject to so-called "peer review." I remind you, this is still before the proposal is formally issued for public comment. These extra steps would, I predict, add years of additional delay. Meanwhile, those workers who are not union members and could not negotiate protections would still suffer dangerous exposures to metalworking fluids. S. 746 makes a bad situation worse.

The UAW has the following specific objections to the provisions in S. 746:

1. The so-called "peer review" provisions close the standard setting process, open the way for industry special pleading, and delay action for no benefit.

The bill's sponsors state that one of their goals is greater transparency for the regulatory process. But a comparison of the bill's peer review provisions to current OSHA procedures shows that enactment of S. 746 would actually result in a process that is less transparent and open.

OSHA procedures require that proposed standards must be presented in a public hearing if any affected party requests the hearing. OSHA must present evidence supporting the proposed standard, including witnesses and documents explaining the health risks, control measures, cost analyses and every detail of the rule. Any participant in the rulemaking may ask questions of OSHA and its witnesses, as well as present their own evidence and comments. In turn, any participant may ask questions of the others, and OSHA staff may ask questions as well. This round robin process is open, on the record and exhaustive. Scientific experts, representatives of unions and employers and government officials take their turn. Workers who are exposed to the hazards also testify. Finally, OSHA must explain and defend the final rule, addressing all the comments and criticisms. This process has been recognized as equivalent to "peer review."[1]

By contrast, the additional "peer review" process envisioned by S. 746 is closed and participation is limited. Before the public gets to participate directly, the agency would be required to appoint a panel of experts. Workers, who know the most about exposures and how to control them, would be shut out of the process. Likewise, all agency employees would be prohibited from participating. The bill specifies that the panels are to be "broadly representative." Presumably they would include representatives of the industry interests that oppose change. Thus, conflict of interest is not only permitted, but practically required. The "peer review" panel may be required to sign confidentiality agreements, which would permit decisions on public health protection to be made -- or not made -- based on secret information. The peer review groups are exempt from the Federal Advisory Committee Act (FACA), which requires balance and open meetings. Thus, the basis for a standard would be subjected to closed-door review, possibly off the record and undocumented, before the standard goes public.

The bill's requirement that panels be "broadly representative" can be interpreted to be contrary to requirement for "balance" in FACA. S. 746 fails to define what "representative" means -- is the issue scientific views or the interests of persons to be protected by the proposed public health action?[2]

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[1] The Presidential Commission on Risk Assessment and Risk Management recognized the value of the OSHA hearing: "In some cases, alternatives to traditional peer review panels may be appropriate. For example, while OSHA uses peer review panels for some complex issues, it relies to a greater extent on trial type rulemaking hearings, that can be quite rigorous. The two approaches should be compared and evaluated against criteria based on agency or cross-agency policies." Vol. II, p. 104

[2] Allowing conflict of interest conflicts with the specific recommendations of the Presidential Commission on Risk Assessment and Risk Management. The Commission states: "The Commission believes that expertise in the technical area under evaluation should be the primary criterion for members of peer review panels. However, potential peer reviewers with financial conflicts should be disqualified from service on peer review panels that could specifically influence regulatory decisions related to the products or interests of their organizations." Volume II, p. 103.

I predict there will be extensive litigation over this issue if the bill's peer review process is allowed to remain subject to judicial review.

Obviously, the extra peer review step mandated by the legislation takes extra time and extra OSHA and stakeholder resources, which could be better spent addressing additional hazards. Quite frankly, this extra step is just one more foothold for interests who simply want no change and whose only goal is to stop any new regulation.[3]

The UAW submits that "peer review" is simply not a model for public health decision making. Traditionally, "peer review" is a set of practices for evaluating research funding proposals and articles submitted to scientific journals. For research funding decisions, discussions are completely confidential, reviewers with institutional conflicts must leave the room when projects are discussed, and reviewers written comments are physically destroyed. For many scientific journals, the authors' names are withheld from the reviewers, and the reviewers are anonymous. The term has been loosely extended to expert panels brought together to justify science-based public policy decisions. Advocates of peer review in the regulatory setting are often those who do this as a large part of their activities. It is true that the National Academy of Sciences advocates peer review, but the NAS is in the peer review business.

2. The bill's detailed specifications for risk assessment and cost benefit analysis are inappropriate, wasteful and will likely lead to prolonged litigation.

The bill's detailed specifications for analyses are designed for exposure to cancer causing chemicals, and perhaps some other chemical hazards. The bill requires comparative risk analysis and substitution risk analysis, which multiplies the amount of paperwork to be done. Each of these elements may provide grounds for a legal challenge to block a protection.

The bill's analytical framework is much less appropriate for safety (acute injury prevention) standards and is difficult to implement for program standards such as a requirement for safety and health programs. It is completely inappropriate for provisions implementing workers' rights. For example, the Occupational Safety and Health Act requires employers to give chemical exposure monitoring results to the workers whose exposure was measured. S. 746 would subject provisions implementing these rights to economic analysis.

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[3]The Presidential Commission on Risk Assessment and Risk Management: "Peer review is unlikely to be needed for every regulatory decision. Implementing a peer review process for every agency decision or every step in a regulatory decision would lead to substantial delay and require excessive resources. The most effective and most efficient use of peer review should be decided case by case, taking into account such issues as the extent to which the scientific basis for the risk assessment or economic analysis might be considered controversial, the economic impact that a decision might have, and agency resource constraints." Vol. II, p. 105.

In addition, the bill's rigid quantitative framework excludes exactly the kind of experiential knowledge that workers and front line management possess. This knowledge is usually called "common sense."

The Committee should also recognize that cost calculations are much less reliable than health risk assessments. These analyses usually wildly overstate the expense of complying with OSHA's standards. This is because OSHA and other agencies generally must depend on cost data generated by the industry to be regulated. Industry usually stonewalls on such simple issues as who is exposed to chemicals at what levels, what specific engineering changes really cost and what process alternatives are available.

As a practical matter, the data to conduct such analyses are potentially available for chemical exposure standards. After the long delay of meeting the specifications in this legislation, a few chemical standards would emerge intact. The protections most damaged would be safety standards, such as for forklift trucks, and program standards.

It is important to stress that the cost benefit analysis required by this legislation runs counter to the provisions of the OSHA statute, as interpreted by the Supreme Court and numerous Courts of Appeals. The terms set by Congress and the interpretation given by the courts are that OSHA health standards must eliminate significant risks and be economically feasible, while other rules must be reasonably necessary and appropriate. OSHA is prohibited by law from using cost benefit analysis as a justification for raising the levels of permitted exposure and increasing the injuries or diseases expected. This begs the question: why should OSHA be required to conduct the analyses proposed in the bill?

Finally, the argument advanced by some that labor unions representing affected workers try to impose needless costs on employers is not credible in the current climate. Workers are worried by threats of plant closure, of work leaving to low regulation havens like Mexico, and are constantly barraged with arguments for increased productivity and efficiency. Costs are a concern. Efficiency and quality are concerns. But health and safety comes first. NAFTA has devastated American manufacturing, but the dire economic predictions for OSHA standards have never been borne out. No OSHA standard has caused the economic disruption predicted by the industries that have created the hazards.

3. This legislation imposes burdensome requirements on even the most minimal, practical and routine regulations to protect employees.

A major rule under this bill could be any rule that costs each US employer, on average, $85 a year.

Virtually any OSHA standard could be a "major rule" subject to the detailed analytical requirements of the legislation. OSHA attempts to protect employees

of over six million employers. Divide this into the $500 million dollar level for a "major rule," and you find that any standard that costs the average employer $85 a year is a "major rule." This is the cost of lighting a few exit signs. You can maybe sweep the floor for $85 a year. In other words, the simplest actions could be delayed by complex analyses and peer review if they apply to a broad range of employers. If this were not enough, the bill empowers OMB to reach down below $85 to designate additional standards for review.

4. The history of OSHA standards shows that the goal of regulatory reform should be speeding the process, not slowing it down.

The UAW's real life experience with OSHA standard setting is simple: OSHA standard setting is stalled.[4] The standard setting process is failing to protect workers. Recent rules on energy lockout, formaldehyde and methylene chloride, championed by the UAW, were completed only after decade long campaigns, including lawsuits to compel action and to toughen standards.

For example, the UAW petitioned for the energy lockout standard in 1979, after an industry consensus standard had been completed. A proposed standard was not issued until 1988, a final standard for general industry not until 1989. At the time, OSHA promised to extend this protection to workers in construction. But as of today, the agency has been unable to extend this protection to construction workers, who remain at increased risk.

The need to increase the pace of safety and health standard setting at OSHA is generally recognized by those in the public health community, including many observers associated with industry. There is a long list of rules already promised but not delivered by OSHA, a few of which I will briefly summarize.

A standard for ergonomics programs would address the largest single cause of pain and disability among American workers today. Musculoskeletal disorders are over half of all disabling injuries in all industry, and nearly 2/3 of all injuries in automobile plants. In August 1990, Secretary of Labor Elizabeth Dole announced that OSHA would develop a standard for ergonomics programs. A pre-proposal version, not yet scheduled for public hearing, is now in SBREFA review. Opponents are using the inside track of SBREFA review to organize opposition and try to block even a public hearing.

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[4]The Presidential Commission on Risk Assessment and Risk Management: "OSHA's limits for chemical exposures (Permissible Exposure Limits, PELs) are out of date, not readily updated, and not sufficiently protective of worker health for millions of American workers. The OSHA PEL update process has been slowed to a crawl by a series of legal challenges. A chemical-by chemical PEL-setting process, based on intensive assessments of toxicity, exposure, risk and feasibility, has proved impractical for all but the highest use chemicals. A more constructive and streamlined process is needed for regulating workplace exposures to a large number of air contaminants." Vol. II, p. 134

Likewise, OSHA has been unable to issue a proposal for a long-promised requirement that employers establish basic safety and health programs. Such a program requirement would mirror several state regulations dating back to the 1970's and '80's. OSHA placed the safety and health program rule on its regulatory agenda in 1993. It has widespread, long-standing support from industry. It is just now emerging from SBREFA review, decades late.

A standard for airborne tuberculosis is urgently needed to protect healthcare workers and patients. A proposal to codify the Centers for Disease Control's 1994 voluntary guidelines has been issued years after this grave threat to health care workers was identified, but an enforceable requirement that health care employers protect their workers is still years away.

The Permissible Exposure Limit Update project, originally started in the Reagan Administration, would adopt consensus recommendations to lower chemical exposure limits for about 400 of the most common industrial chemicals to which workers are exposed. OSHA's current limits for these materials were established in 1968 and have never been revised.

The standard for silica has not been addressed since an Advance Notice of Proposed Rulemaking issued in the Ford Administration. According to OSHA, MSHA and NIOSH the current standard permits more than 250 workers a year to die from silicosis and leaves more than 100,000 workers at high risk of developing lung disease.

The time and resources OSHA must spend on economic analyses limits the progress the agency can make on new standards. For each regulatory action, OSHA already engages in an extensive effort at "costing out" rules, even when cost is not the source of significant opposition. Limited staff and the absence of industry data make regulatory analysis the main obstacle to OSHA issuing even a proposal. The analysis has to be done even before the proposal is issued, and becomes a straight jacket for changes in the rule in response to public comment.

The burden has shifted to the agency to prove that a regulation to protect human life and health is not only feasible, but cheap. Industry and its allies may stall action by nit-picking the methods and economic data without even having to argue the significance of the outcome. As OSHA and proponents of safety and health rules have become more efficient about collecting data and doing such analyses, opponents now want to raise the bar by adding net benefits analysis, regulatory flexibility analysis, comparative risk analysis and substitution risk analysis.

5. True Regulatory Reform would go in the opposite direction from S. 746.

Based on my 25 years experience in the UAW's health and safety department, I believe the main problem in updating protections at OSHA is the lengthy time spent in the pre-proposal, pre-hearing stages of the process. This legislation loads even more of the process into the pre-proposal stages. It is exactly the opposite of what needs to be done.

Once a proposed standard emerges onto the public stage in the open hearing process, things begin to move. Industry sees what is really required, labor and public health advocates see who is left unprotected and the real costs finally emerge. Each side marshals its evidence, tests its arguments and has its "day in court." Practitioners speak, not lobbyists and lawyers.

The productivity problem at OSHA is not simply the duration of the standards process. The problem is that the agency has resources to deal with only a few issues at a time, and each of these takes over a decade.

My specific recommendations for regulatory reform are:

- Clarify that the existing OSHA hearing process exceeds the transparency, openness and balance of the proposed new peer review process and existing regulatory oversight.

- Move the SBREFA review and pre-proposal OMB review entirely into the open record of rulemaking, and into the OSHA public hearing where these views can be questioned by all participants.

- Provide the same access to judicial remedies for parties who wish to challenge the agency's failure to act to protect as to those who would oppose action.

- Adequately fund OSHA so that it is able to carry out its statutory mandate to protect America workers from work-related injuries and illnesses.

Conclusion

No one who looks at OSHA's dismal rulemaking record over the past decade can reasonably argue that the agency has been too zealous in the protection of the American worker, or has taken regulatory action that poses an economic threat to American industry or our economy. To the contrary, OSHA's regulatory process has been too slow and unresponsive, even when confronted with serious hazards to the safety and health of our members and workers in general. Recognized threats to health and safety are being ignored, and American workers suffer death, injury, illness and disability at a shamefully high rate as a

result. The absence of a comprehensive approach to workplace health and safety threats places our nation's economic health in jeopardy: workers who are injured or made ill or killed on the job are a drain on our economy; unsafe work sites are inefficient.

The provisions in S. 746 are imposed on public health agencies, but the burden is borne by the working people exposed to the hazards and suffering the consequences. Our members cannot understand why it takes 10 or 15 or 20 years to change a standard after science or common sense shows it is not protective. That's a time when government is telling our members something is safe when it is not safe. Now our members are asking why legislation is being considered to make it even more difficult to get new protections against hazards that put their lives, limbs and health in danger.

For all of these reasons, the UAW strongly opposes the proposed "Regulatory Improvement Act of 1999" (S. 746). We urge the members of this Committee and the entire Senate to reject this legislation.

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TESTIMONY OF DAVID C. VLADECK, ESQ.
DIRECTOR, PUBLIC CITIZEN LITIGATION GROUP
BEFORE THE SENATE COMMITTEE ON GOVERNMENTAL AFFAIRS
ON S. 746, THE REGULATORY IMPROVEMENT ACT OF 1999

April 21, 1999

Mr. Chairman and members of the Committee, thank you for the opportunity to testify this morning on S. 746, the Regulatory Improvement Act of 1999. Before I turn to my substantive remarks, let me briefly sketch the background and experience I bring to the subject.

I am the Director of Public Citizen Litigation Group, the legal arm of Public Citizen, a nationwide advocacy organization with 150,000 members. For more than twenty-five years we have represented consumer groups, labor unions, worker groups, and public health organizations in standard-setting proceedings and in litigation involving the OSHA, EPA, FDA, USDA, NHTSA and other health and safety agencies. Public Citizen is also a member of Citizens for Sensible Safeguards, a broad-based coalition of consumer, environmental, civil rights, labor and health care organizations opposed to legislative proposals that would undermine federal safeguards. I am also currently a Visiting Professor of Law at Georgetown University Law Center.

Public Citizen's extensive, first-hand experience with the regulatory process gives us substantial insight into the way our system now operates. My testimony today addresses the question of how the bill before you -- S. 746 as introduced March 25, 1999 -- would affect basic health, safety, environmental and civil rights protections if it were to become law. It is quite true that this year's bill differs from last year's bill, just as last year's differed from the omnibus regulatory procedure bills introduced in the 104th Congress. But in our view the questions that must be answered about S. 746 of 1999 are not how it replicates or differs from previous years' bills; but rather, how would it change current law, and what would be the real world impact of those changes?

The short answer is that S. 746 would do real harm to public health, safety, environmental and civil rights safeguards. I want to use my time today to present concrete examples of how this bill's "one size fits all" prescriptions would work to block or weaken urgently needed safeguards.

Law of unintended consequences

But first, let me make one point about S. 746 and the law of unintended consequences. The scope of what S. 746 covers is extremely broad but nowhere is it actually defined. While it's understood that the bill would apply to rules to protect the environmental and worker safety, it is not generally known that it would also cover rules to protect nursing home patients from abuse and neglect, or to ensure access to public accommodations for persons with disabilities. Furthermore, we know of no analysis that compares S. 746's prescriptive risk assessment, cost-benefit and net benefits analyses, and peer review provisions with the types of analysis and standards that are currently required by the various statutes to which S. 746 would apply. Are

they duplicative? Are they in conflict? Will they actually improve the quality of agency rulemaking, or will they squander already scarce agency resources?

We are not alone in noting the absence of this information. In a July 31, 1998, letter to OMB Director Jack Lew, House Minority Leader Richard Gephardt, Minority Whip David Bonier, and the Ranking Minority Members of the House Committees with jurisdiction over regulatory agencies asked those same questions. (Letter and questions attached) It is our understanding that, to date, they have not been answered. The greater the unknowns, the more likely that a such a sweeping change in law as S. 746 requires will result in significant unintended consequences.

Regulatory Obstacle Course

S. 746 would change current law by imposing highly prescriptive risk assessment, cost-benefit analyses, net benefits determination, and peer review mandates on the health, safety, environmental protection and civil rights regulatory process. The real world impact would do serious damage to the ability of federal agencies to protect public health, safety, the environment, and civil rights. S. 746's "one size fits all" prescriptions would:

1. Add months if not years of delay to an already torturously slow process -- it takes OSHA and EPA on average ten years to issue a major rule;
2. Tilt the playing field to an even greater degree than is already the case toward less protective safeguards in order to lower industry compliance costs;
3. Make the regulatory process less democratic and less transparent than it is at present; and
4. Create new grounds for industry opponents to successfully challenge public safeguards in court.

To give you one particularly vivid illustration of the gridlock that now paralyzes our regulatory agencies, let me recount the problems that 200,000 American workers face in having OSHA address the very serious health hazards posed by hexavalant chromium. There is no longer any scientific debate that hexavalant chromium is a potent lung carcinogen. In 1975 and again in 1988, the National Institute for Occupational Safety and Health (NIOSH) urged OSHA to reduce the permissible level of exposure for hexavalant chromium 100-fold. NIOSH's concern is that the lung cancer risk from hexavalant chromium is intolerably high. OSHA's scientists agree. Their detailed risk assessment shows a range of 88 to 342 excess lung cancer deaths per 1,000 workers exposed to hexavalant chromium levels of *half* of what is currently permitted over their working lives. This risk is grave by any measure.

What, you ask, has the agency done in the face of a health threat of this magnitude? To date, the answer is nothing. My clients, the Oil, Chemical and Atomic Workers Union and Public Citizen Health Research Group, filed a rulemaking petition with OSHA in 1993 asking the agency to address the health threat posed to workers by hexavalant chromium. Since that time, OSHA has repeatedly acknowledged the gravity of the risk workers are facing, and has

pledged to address it swiftly as it can. But the agency, after six years, is still probably at least a year away from publishing a notice of proposed rulemaking. Meanwhile, 200,000 American workers are paying for this regulatory paralysis with their health and well-being.

Instead of tackling the problems of agency paralysis -- which puts millions of Americans at risk, just like the 200,000 workers exposed to hexavalant chromium -- S. 746 adds to it. Not only is S. 746 highly prescriptive in terms of the risk assessment and cost benefit analysis it requires, slowing and complicating the agencies' preparation of those documents; but S. 746 also mandates cumbersome peer review procedures that will give industry a preferred place in the rulemaking and shut the public out, and it expands the scope of judicial review to give industry new weapons to challenge agency rules.

Let me explain in greater detail how the "regulatory obstacle course" S. 746 would erect would work in practice.

Risk Assessment:

S. 746 for the first time imposes a statutory requirement on agencies to conduct risk assessments according to its detailed prescription for every major rule [i.e., one with annual costs of more than $100 million] "the primary purpose of which is to address health, safety or environmental risk." S. 746's prescriptive steps must also be followed for risk assessments unrelated to regulation that are identified by OMB as likely to have a cost impact of $100 million or more annually. Section 624(a)(1)(A).

This is an extraordinarily broad requirement. Agencies will be compelled to perform risk assessments even when the risks are perfectly apparent, as they are with foodborne toxins such as salmonella, listeria, and E. coli 0157. There is no comparable provision in Executive Order 12866, nor have some health and safety agencies routinely prepared risk assessments in the past. For example, although the economic impact of the FDA tobacco rule exceeds the $100 million annual threshold, no formal risk assessment was prepared to support it, although one would be required by S. 746.

Food safety protections are an ideal case study to explain why S. 746's risk assessment mandate would be so damaging. In the last years, we have become all too aware of the deadly risk which microbial pathogens like E. coli 0157, listeria, salmonella enteritidis, and cryptosporidia pose to the safety of our nation's food supply. In 1993, after the tragic deaths of children caused by E. coli 0157 in Jack-in-the-Box hamburgers, USDA initiated rulemaking to modernize the century old "poke and sniff" meat inspection system. That resulted in the 1996 Hazard Analysis and Critical Control Point (HACCP) rule, a performance-based system that relies on microbial testing to verify the effectiveness of a meat and poultry plant's pathogen reduction plan. Deaths and serious illness from microbial pathogens have also been linked to lettuce, fresh fruit, processed luncheon meats, hot dogs, and shellfish. USDA and FDA are currently exploring how best to protect the public.

Had S. 746 been in effect, USDA could not have initiated the HACCP rule, or, at best, would have been severely hampered by it. That is because no risk assessment of the sort prescribed by the bill was conducted, or could have been conducted. Data to demonstrate and measure risk of foodborne illness that would satisfy S. 746's prescriptive methodology were not, and still are not, available. So even though the public danger was clear and the need for protection urgent, S. 746 would have required USDA to devote months and perhaps years to collecting and analyzing data proving the obvious before doing anything else. If S. 746 becomes law, its risk assessment mandate will block USDA and FDA in the future from acting swiftly to prevent foodborne illness from microbial pathogens in fresh fruit and produce or prepared meats.

S. 746's "one size fits all" risk assessment mandate doesn't "fit" food safety. That is not because USDA and FDA rules are not science based. To the contrary, the HACCP system was developed by the National Academy of Sciences; numerous scientific studies underlie the agencies' food safety work. The agencies are developing a *process risk model* of risk assessment to identify the points in the farm-to-table continuum where the risk of contamination is the greatest. When it comes to protecting the nation's food supply, S. 746 is bad science: It mandates the wrong risk assessment model be used for the wrong purpose at the wrong time.

There are three other problems with the S. 746 risk assessment provision. First, the bill requires years of work to take place even before the publication of the Notice of Proposed Rulemaking (NPRM), which, under the APA, is the *first* formal step in the rulemaking process. Under the bill, risk assessment has to be done very early in the pre-NPRM process, both to allow for peer review that Section 625(h) says shall occur before the NPRM, and because the agency cannot publish a NPRM without at least a preliminary risk assessment and cost-benefit analysis. *See* Section 623. Indeed, Section 623(b)(2)(C) requires the initial cost-benefit analysis to evaluate the results of the risk assessment. As a result, agencies will have no choice but to restructure their work. Agencies will first have to prepare, with peer review oversight and public input, their risk assessment. Then the agency will have to conduct at least a preliminary cost-benefit analysis. And all of this work -- which could take years to complete -- must be done even prior to the publication of the NPRM, because Section 623 requires the initial regulatory analysis to include both documents. Had S. 746's requirements been in place when the Agriculture Department was trying to cope with outbreaks of E. coli 0157, it would have crippled the Department's ability to respond.

Second, the risk assessment provision establishes hurdles the agencies cannot possibly overcome. In two separate provisions, agencies are directed to consider *all* relevant, reasonably available and reliable information. One provision, Section 624(e), instructs the agency to consider all such information in preparing each risk assessment. The second provision, Section 624(e)(2), directs agencies to consider all such information in making the scientific assumptions that underlie the agency's risk assessment. Simply to describe the task these provisions direct the agencies to tackle demonstrates that it is undoable. Nor does this requirement make sense. Assume for the moment that there are fifty basic treatises on risk assessment. Is it really Congress's intention to require the agency to consider each treatise, even though, in the language

of Section 624(c)(2), they plainly are "reasonably available, relevant and reliable"? What about the FDA's tobacco rule? Does Congress seriously intend to saddle the FDA with reviewing *every* available and conceivably relevant study to determine whether it is reliable so that the agency can assess the risks of smoking? This requirement guarantees regulatory paralysis. Ask yourself this question: Could Congress function if it were subject to the same mandate as a precondition to legislating? I have my doubts.

Third, although risk assessments have been subjected to judicial review in the past, nothing in the APA specifically directs reviewing courts to examine the risk assessment, as S. 746 would require. As discussed more fully below, S. 746 marks a substantial change which will almost certainly intensify judicial review of risk assessments, and one that will inevitably force agencies to put more time and effort into polishing their risk assessment than they do now -- as will the bill's prescription that risk assessment studies be peer reviewed, and that agencies respond in writing to written comments by peer reviewers.

Cost-benefit analysis and net benefit determination

We recognize that most agencies have been required to perform cost-benefit analyses for significant rules for quite some time. But until now, the cost-benefit analyses played a specific and highly limited role. They are prepared to ensure that agencies achieve their regulatory objectives with due regard for cost and in the most economically efficient way possible consistent with their statutory mandates. Cost-benefit analyses are available for public and OMB review, and are the subject of probing, on-the-record dialogue between the agency and regulated parties. But, by and large, they are not subject to judicial review, especially for those agencies -- like the health and safety agencies -- that operate under statutes that foreclose reliance on cost-benefit considerations in standard setting.

S. 746 topples that understanding. To begin with, S. 746 sets highly detailed and prescriptive requirements for cost-benefit analyses and mandates inquiries agencies do not at present ordinarily undertake. For instance, what purpose is served by requiring OSHA to evaluate numerous options forbidden to it by statute, such as the option of doing nothing, as Section 623(b)(2)(A)(iv)(I) requires? And why should OSHA evaluate "a range of regulatory options," when its statute gives the agency an unequivocal mandate to worry first and foremost about worker protection, not about lower-cost but less protective options?

Moreover, S. 746 requires that an agency do one of two things before promulgating a final rule: (1) Certify that its rule optimizes economic efficiency by achieving "the rule making objective in a more cost–effective manner, or with greater net benefits, than the other reasonable alternatives considered by the agency," *see* Section 623(d)(1)(A), or (2) justify why it failed to impose what S. 746's methodology determines to be the single most economically rational option. We believe that the premise embodied in S. 746 – that there is a single rulemaking course that is economically optimal – is nothing but a chimera.

But the real vice of S. 746 is that it will rightly be seen by agencies as a mandate to put considerations of economic efficiency first, even when the agency's organic statute dictates otherwise. To put it bluntly, the take home message of S. 746 to agencies is to optimize the economic benefits of the regulation relative to costs. But many agencies are forbidden from doing that. OSHA, for example, is instructed by section 6(b)(5) of the Occupational Safety and Health Act, to set the most protective standard feasible, limited only by technological feasibility (is compliance technically possible?) and economic feasibility (are the compliance costs so high that they will result in significant economic dislocation for the industry as a whole?). Put another way, OSHA is not permitted to say, for instance, that $100 million is too much to spend to save fifty workers' lives, so long as there is an available solution that is technologically feasible and that would not cause the industry serious economic dislocation. OSHA must impose the $100 million standard, even if a $50 million standard would save forty of those lives. Forcing OSHA to address these less protective (and legally foreclosed) options does not enhance the quality of the agency's decision-making -- it only dissipates scarce agency resources.

S. 746 says that it does not change or modify Congress' instruction to OSHA. Section 622. That literally is correct. Under S. 746, OSHA theoretically remains free to select the more protective rule, provided that it explains that the more expensive rule is required by the OSH Act and puts its analysis of the lower cost option in the record.

But there are two problems with this scenario. First, it is far from clear that the hydraulic pressure imposed on the agency by S. 746 to moderate its rule to achieve lower costs will be resistible by regulators. If you were an OSHA Administrator confronted with the choice I've just outlined, which route would you take? S. 746 and the OSH Act give an OSHA Administrator two diametrically opposed messages -- the OSH Act says protect workers at virtually any cost; S. 746 says, whatever you do, make sure you place economic optimality above all other values. These are contradictory messages that simply cannot be reconciled and S. 746 will push agencies towards saving money, not lives.

Second, even if the net benefits test, standing alone, does not push agencies towards less protective rules, when its impact is combined with peer review intervention and the looming presence of judicial review, agencies will face enormous pressure to go in the direction of economic efficiency -- even at the expense of the public protections.

Peer Review

S. 746 calls for peer review of risk assessments prepared in support of a major rule or as ordered by OMB and of cost-benefit analyses for rules with more than $500 million in annual costs. Section 625. This provision is a misnomer. As commonly understood, the purpose of peer review is to bring neutral, disinterested expertise to bear on a scientific or technical issue. But S. 746 really provides for "partisan review," because it assumes that parties with a direct stake in the outcome of the rulemaking will participate in the peer review process.

The potential for self-interested members of peer review panels to abuse their positions is made all the more severe because the panels are permitted to operate in secret, closed-door sessions, with no public oversight of the process. Astonishingly, panels are permitted to meet in secret, keep no minutes, and keep their deliberations from public view. There is no requirement that the panels represent competing points of view; indeed, the only "balance" that is required is that panel *reports* must contain a "balanced" presentation of the issues. How an unbalanced panel will issue balanced reports is not addressed by the bill. Making matters worse, it is a virtual certainty that the panels will be not be broadly representative, no matter what the statute says. The reality is that the only stakeholder in the regulatory process that can afford to sponsor panel members is big business. Labor unions, environmental and civil rights organizations, and public interest groups do not have staffs of scientists or economists who can take time out from their work schedules to participate in these panels. Nor do they have the financial wherewithal to hire these experts or to sponsor them in academia, as the regulated industry is able to do. And, for no reason that is apparent, agency experts are excluded, despite the knowledge and technical competence they could add to the peer review committee's deliberations.

We are also troubled by the language in section 625(b)(1)(E) that allows peer review panels to review secret submissions, subject to confidentiality agreements. Giving peer review panels access to information denied to the public confirms our point that these panels have a preferred place at the rulemaking table, and will be able to exert influence on the rulemaking far beyond the ability of other citizens. Moreover, the idea that the agency will consider information that is off-limits to the general public in preparing key regulatory documents is a strange one, which, insofar as we are aware, has no clear anchor in existing law. The statutes that define what constitutes rulemaking records to do not contemplate portions of the record being fenced-off from the public. And to the extent that agency personnel have access to such information, it ought to be closely held and not shared with peer reviewers, particularly those with a financial stake in the outcome of the rule. That would again provide an enormous advantage to the preferred few that participate in the peer review process.

We disagree with the defense of this provision raised in some quarters, namely that this is a benign process for the agency to receive expert assistance on highly technical matters in a systematic way. There are two problems with this justification. First, it overlooks that the APA itself establishes that system through the requirement of notice and comment rulemaking. Any suggestion that the current system does not afford interested parties the opportunity to offer their expert views on agency risk assessments and cost-benefit analyses is nonsense. Second, it ignores the fact that the peer review provision does not construct a one-way street, with information flowing only to the agency. To the contrary, the agency is required to respond, in writing, to significant peer review comments, giving peer review panel members enormous leverage in the rulemaking process. It is counter to basic democratic principles to empower a select few to be given a privileged place in the rulemaking process, but, make no mistake, that is precisely what this provision does.

The final problem with the peer review mandate in S. 746 is time and money. This process will be extremely time-consuming -- and tens of thousands of dollars per panel will be

diverted from other important priorities. For agencies already cash-starved by budget reductions, having to bear this burden will sap their ability to do their work. Congress should not impose this "unfunded mandate" on the agencies.

Expansion of OMB authority and secrecy

S. 746 represents a capitulation by Congress on an issue that has provoked considerable passion in the past -- namely, should the President be given authority to review agency rules? Whatever the merits of presidential assertions of power to review agency rules, it is quite another thing for Congress to surrender that power to the President. S. 746 does just that. It directs the President to "establish a process for the review and coordination of Federal regulatory actions," *see* Section 632(b), and to assign the task of reviewing federal regulatory actions to the Director of the Office of Information and Regulatory Affairs at OMB. Finally, S. 746 dictates, at least in outline form, the procedures OMB must employ in reviewing rules. We are surprised that Congress would endorse this view, particularly given the opposition of many in Congress to centralized Presidential review and the efforts Congress has taken in the past to circumscribe OMB's power.

But apart from our disagreement about the wisdom of centralized OMB review, there are serious problems with S. 746. Foremost among them is that the procedural rules it dictates are less transparent and accountable than those that exist under Executive Order 12866. For example, OMB would no longer have to put in writing why it is disapproving an agency rule. Agencies would no longer have to log "substantive" messages received from non-governmental entities regarding rules under review; only "significant" meetings and calls would have to be logged. The bill also reverses changes made by the Clinton Administration to establish a fixed 90-day OMB review period, with the possibility of one 30-day extension if requested jointly by both the Agency Director and the OMB Director. Under S. 746, OMB would be able unilaterally to extend its review of rules *indefinitely*. Section 632(d)(2). Given the abuses that have taken place in the past, where OMB literally held important rules hostage until agencies relented and made changes OMB wanted, Congress should outlaw this practice, not bless it.

We understand that nothing in S. 746 would forbid an enlightened Administration from adopting procedures that provide for greater accountability and transparency. But our experience with OMB has shown that not all Administrations share the view that OMB's review process should be an open one. If Congress chooses to legislate in this area, it ought to do so with the understanding that the procedural safeguards it prescribes guarantee full OMB accountability to the public.

Judicial Review

The judicial review provision of S. 746 is bound to cause serious mischief in the courts, and will force agencies to regulate defensively, generally by doing less rather than more. There are no fewer than four serious problems with this provision.

First, like any provision of a statute, the judicial review provision will not be read in isolation. Rather, it will be read in context. Courts will try to understand the purpose of the Act in determining the scope and intensity of judicial review. In so doing, they will get what is, at best, a mixed message. For although S. 746 professes that it is not intended to displace the decisional standards set in the agency's organic statutes that generally look only to maximizing public protection, S. 746 sends a diametrically opposed message to agencies -- maximize economic efficiency. That message will not be lost on reviewing courts.

Second, S. 746 directs the courts to review the agency's risk assessment and cost-benefit analyses. Although risk assessments have always been made part of the record on judicial review, that is not true of cost-benefit analyses; under the Executive Orders, they have *not* been part of the judicial review record. Again, Congress' explicit direction that the cost-benefit analysis must be considered by the reviewing court is significant; it too sends a message that Congress wants the courts to ensure that the final rule is economically efficient.

Third, S. 746 directs a reviewing court to consider the agency's "net benefits" test. This provision is the most telling of all. The function of the net benefits test is to force the agency to identify one rulemaking option that is the most economically efficient in achieving the agency's rulemaking objectives. Where an agency fails to select that option, it is required to explain its reasons and to "describe any reasonable alternative considered by the agency that would be likely to provide benefits that justify the costs of the rule and be likely to substantially achieve the rule making objective in a more cost-effective manner, or with greater net benefits, than the alternative selected by the agency." This requirement places the agency in a highly vulnerable position in a judicial review proceeding. Regardless of what the agency's underlying mandate dictates, the court will measure the agency's rulemaking choice against S. 746's net benefits test and the more cost-effective option the agency must describe. That is a prescription for judicial invalidation of the agency's rule.

Finally, S. 746 raises the specter of agency rules being set aside or remanded because the agency failed to perform its cost-benefit analysis, risk assessment, or net benefits analysis in the manner prescribed by Act. This is a serious problem that marks a significant change from prior versions of the bill. In a nutshell, the problem is this. The Act sets up highly prescriptive standards for conducting cost-benefit analyses and risk assessments; it also spells out in detail precisely how an agency must conduct its net benefits test.[1] Section 627(e) says that "[i]f an agency fails to perform" these analyses, the rule may be set aside or remanded. To be sure, a court could read the language in Section 627(e) to apply only when an agency made no pretense

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[1] For instance, a party challenging an agency rule might contend that the cost-benefit analysis was not performed in accordance with the requirements set forth in Section 623. Since the Act itself defines "cost-benefit analysis" to mean one "that is prepared in accordance with the requirements of this subchapter at the level of detail appropriate and practicable for reasoned decisionmaking on the matter involved," an agency arguably fails to "perform" an analysis when it departs in any way from the requirements set forth in Section 623.

of performing these functions. But that is not what the Act now says.[2] There is no qualifier like "completely" or "entirely" to signal to a reviewing court that that is the sort of failure Congress sought to guard against. Moreover, courts will recognize that agencies are not likely to shirk these responsibilities entirely. Rather, courts are likely to measure whether an agency has "perform[ed]" these analyses against the yardsticks established in the statute. If the agency has not followed the statute to the letter, a court might well rule that it has not "perform[ed]" the required analysis and set aside the rule on that basis alone. That could have disastrous consequences for the agency.

Let me end my discussion of the pitfalls of the judicial review provision in S. 746 by illustrating how it creates a Catch-22 situation for health and safety agencies. Imagine that you are a conscientious administrator who is attempting to be faithful to the Clean Air Act's mandate to require maximum achievable control technology to reduce airborne toxins. Under S. 746, you will have conducted cost-benefit analyses of a range of regulatory options, and made a determination that one single option is the most cost-effective or shows the greatest "net benefits." That will undoubtedly be an option that provides less protection that the Clean Air Act, read by itself, would require. Here's your dilemma:

- If you make the determination that the most protective option is the one with the greatest net benefits, the rule may be overturned as arbitrary and capricious because the record does not contain sufficient data and evidence to prove that case under the "one size fits all" cost-benefit tests of S. 746.

- But if you determine that the most protective option fails the net benefits test, and then choose it anyway on the grounds that the Clean Air Act so requires, the rule may be overturned because a court finds that explanation unreasonable. After all, you have just made a record that there is another option that is more cost-effective, or shows greater net benefits.

Either way you go, the more protective rule will be in legal jeopardy. And making a record that you have chosen a regulatory option that is not the most cost-effective would also, of course, put the rule in substantial political jeopardy in terms of OMB and congressional oversight.

The problem is the spotlight S. 746 focuses on risk assessments and cost-benefit analyses and its emphasis on economic concerns over humanistic values. Despite its carefully couched text, the one message that trumps all others in S. 746 is that Congress wants regulators to put cost concerns on the front burner. Even though Section 622 of S. 746 tells courts that it does not supplant the substantive standards and the range of regulatory options the agency has the

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[2] A reviewing court might also find it significant that prior versions of this legislation have included qualifying language. Glenn-Chafee's judicial review provisions would have provided for remand only if the agency "entirely failed to perform" the required analytical tasks. And the Administration proposed that language to that effect be added to S. 981 in the Raines letter of March, 1998.

authority to adopt under the underlying statute, courts must seek to effectuate its provisions as well as other provisions of law. A court could reach the common-sense conclusion that Congress did not want the economic analytical requirements of S. 746 to be an empty gesture and see S. 746 as a message from Congress to insist on a far higher degree of economic justification for regulatory choices than was the rule in the past.

Comparative risk analysis/standardization of risk assessment and cost-benefit analysis

Section 624(g) directs agencies to engage in comparative risk analysis, that is, to compare the risk the agency is seeking to regulate with estimates of human risk that are familiar to and routinely encountered by the general public, and to discuss this comparison in its risk assessment. Comparative risk analysis is a highly controversial technique; this is a mandate to compare risks that are as dissimilar as apples and oranges. Section 630(a)(3) contemplates using comparative risk analysis for government and agency priority setting. This is particularly unjustified, since it can actually skew the setting of priorities in an irrational way. Risks that are easily quantified automatically go to the head of the list, while other risks -- that may be far more serious, but for which the data are lacking -- languish at the bottom. That is not rational priority setting. And it is unwise to enshrine a emerging, nascent technique like comparative risk assessment into law, especially given the enormous uncertainties that plague the underlying data.

Section 628 lays out a timeline for OMB, the Council on Economic Advisors, and the Office of Science and Technology Policy to move toward standardizing agency cost-benefit and risk assessment activities. We do not believe that standardization is appropriate for either risk assessment or cost-benefit analysis. Risk assessment is a relatively young science; the methodologies under development at USDA in the "farm to table" food safety initiative serve different purposes, and thus vary significantly, from an EPA risk analysis of environmental toxins. OSHA and EPA use different methodologies in conducting risk assessment to regulate carcinogens, because the groups they are charged with protecting vary so widely. To suggest, as does S. 746, that the time has come to make risk assessments "consistent" is to ignore the fact that agencies have profoundly different missions.

Conclusion

My testimony today has used real world examples of real world harm that would reasonably and predictably result if S. 746 were to become law. Based both on the known damage the bill would do, and the likelihood of major unintended consequences from what is not known, we believe Congress and this Committee should reject this legislation. Nothing in this bill solves the real problems our regulatory system faces by streamlining the administrative process in a way that unshackles the agencies; nothing helps agencies fill the gaps that threaten our safety net of protections. These are the real problems which Congress and this Committee ought to address.

Thank you for inviting me to appear before you today. I would be happy to answer any questions you might have.

attachments

American Chemical Society

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Edel Wasserman
President-Elect, 1998
President, 1999
Immediate Past President, 2000

April 14, 1999

The Honorable Fred Thompson
Chairman
Committee on Government Affairs
United States Senate
Washington, D.C. 20510

The Honorable Carl Levin
Ranking Minority Member
Committee on Government Affairs
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman and Senator Levin:

I am writing to express the continuing support of the American Chemical Society (ACS) for your efforts to craft regulatory improvement legislation. This support is based on the ACS conclusion that the *Regulatory Improvement Act of 1999* (S.746) will improve the quality of regulatory decisions and enhance public understanding of and participation in the regulatory process.

I have attached our comments that were originally sent to you last year in conjunction with the *Regulatory Improvement Act of 1997*. Many of these suggestions for improving the legislation are still relevant to the current version of the bill.

The ACS is a scientific and educational organization with a membership of nearly 159,000 chemical scientists and engineers. The Society is recognized as a world leader in fostering scientific education and research and in promoting the public's understanding of science. Over the years, the Society has been very active in encouraging improvements in risk assessment and in the scientific basis for regulation.

We hope this is useful as you and your colleagues continue consideration of the legislation. In the meantime, if you have any questions concerning our position, please call Flint Lewis of the ACS Office of Legislative and Government Affairs at (202) 872-4477. Thank you for your consideration.

Sincerely,

Ed Wasserman

Ed Wasserman

Enclosure

Statement of the

American Chemical Society

On the Regulatory Improvement Act

The American Chemical Society (ACS) has carefully reviewed the Regulatory Improvement Act and voices its strong support for the bill. ACS is the largest scientific society in the world, and it has been very active in promoting improvements in risk assessment and the scientific basis of regulation. The Society believes that enactment of this legislation will improve not only the quality of regulatory decisions, but also will enhance public understanding and support of vital government actions. ACS urges Congress, therefore, to pass this bill into law.

The legislation integrates with and builds upon current regulatory programs. The bill codifies many aspects of regulatory analysis included in Executive Order 12866, issued by the Clinton Administration in 1993. This codification is desirable to give continuity to the regulatory analysis efforts, to provide a basis for updating guidance, and to provide a framework for research.

The American Chemical Society sees the proposal as consistent with and an extension of the "Reinvent Government" initiative. Provisions in the bill for consideration of non-regulatory approaches are consistent with some current initiatives such as pollution prevention and various voluntary and partnership approaches being pursued by some agencies, including the Environmental Protection Agency (EPA), the Occupational Safety and Health Administration, and the Food and Drug Administration (FDA).
In the Society's analysis, the bill's resource burden on the agencies will be minimal. As the above example shows, the efforts required of agencies are already carried out to a great extent, but in a less orderly, disciplined, and/or transparent manner. Further, much of any given agency's workload is not involved with major rules and, thus, is outside the scope of this bill.

In the following appendix, ACS emphasizes several provisions of the bill that are crucial for achieving sound risk assessment; emphasizes that the bill integrates and builds from existing regulatory programs; and offers several suggestions that it believes will clarify and improve the provisions of the bill.

APPENDIX

Provisions of The Bill Which Are Key to Improving Risk Assessment and Cost-Benefit Analysis.

a. *Principles for a Sound Legislative Framework for Risk Related Regulations (Section 624).*

The Society has been an advocate for the development and articulation of a framework of principles for risk assessment. The foundation for principles of risk assessment has been laid out by three committees of the National Academy of Sciences (NAS) in 1983, 1994, and 1996, and by a Presidential/Congressional Commission on Risk Assessment and Risk Management in 1997. ACS believes that the provisions of Section 624 are a noteworthy articulation of the conclusions reached by the NAS committees and the Commission. The Society urges that this section be retained in its present form.

In particular, ACS strongly supports the emphasis placed on the principles of using "reliable and reasonably available scientific information" (Section 624 (b)) and of organizing and communicating the risk assessment in an orderly, understandable, and timely manner (Section 624 (d) through (g)).

b. *Peer Review of Risk Assessments (Section 625).*

ACS believes that the bill builds on the conclusions of several important studies. Both the NAS report on *Science and Judgment in Risk Assessment* and the *Presidential/Congressional Commission Report on Risk Assessment and Risk Management in Regulatory Decision Making* underscore the need for peer review by experts outside a regulatory agency. Furthermore, both EPA and FDA have experience with peer review panels that demonstrates the usefulness of expert scientific input and that peer review can be conducted without unreasonably delaying the regulatory process.

In its testimony, the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget expressed concern that a peer review prior to the time that an agency issues a Notice of Proposed Rule Making (NPRM) may be premature because of only limited information. The Society recognizes that an extensive formal peer review at the time of the NPRM may not be cost effective in some instances. As an alternative to a peer review at this stage, ACS believes that the bill's language could provide for agency discretion to either convene a peer review panel or to rely on peer consultation and discussion with a peer panel. The Society believes that this consultation alternative could involve discussion of the merits of data available to the agency at the time and further identification of the types of questions to be addressed in preparation of the risk assessment.

c. *Guidelines for Risk Assessment and Cost-Benefit Analysis (Section 628 (a)).*

The Society believes that guidelines are very important to provide consistency in the analytical processes across agencies in order to build public confidence and to assure that methodology is consistent with scientific thought. As demonstrated by some of EPA's risk assessment guidance, guidelines can be constructed to provide a framework that accommodates various types of data and circumstances. Development of guidelines by OIRA, the Office of Science and Technology Policy, and the agencies can be done in a way that overcomes the fears of a "cookie-cutter" approach to assessment and analysis.

d. Research to Permit Assessment of Comparative Risks (Sections 628 (c)(2)(B) and 629 (b)(2)).

One of the major problems in setting rational priorities for regulation or in evaluating the benefits of a particular regulation is the difficulty and complexity of comparing different risks and dangers, e.g., an aspect of human risk with an aspect of environmental risk, or an aspect of highway danger. Few formal studies have been conducted to date. ACS believes that government sponsorship of such research is needed; the Society feels that the bill identifies two very worthwhile and timely studies.

e. The Distinction of Scientific Factors from Economic and Social Factors.

The bill provides for the separate analysis of risk and cost-benefit, and the ACS is supportive of maintaining this distinction. In this way, information is presented factually and with expert judgment so that risk managers and the public can integrate the risk factors with other economic, social, and political factors.

Suggestions for Improving The Bill.

ACS believes that the bill is a very positive and constructive effort toward improving the regulatory process. However, ACS has several suggestions that would improve the clarity and workability of the bill.

1. Since an NAS report in 1983, the concept of dose-response evaluation has been generally accepted as an integral part of risk assessment. The Society, therefore, suggests that Section 621 (9) defining risk assessment include the term "dose-response."

2. The quality of substance-specific data gathered from environmental analysis is subject to a wide range of confidence levels in terms of both the identification and the concentration levels of the substances being analyzed. If the confidence level for either the substance identification or the substance concentration is low, then the variability of the resulting risk assessments will be high.

   In the absence of relevant and reliable scientific data when information based on assumptions is used, if the confidence levels selected do not appropriately represent the confidence levels that can be obtained using current technology, then the resulting environmental risk assessments will be incorrect. Thus, it is important that the confidence levels used for substance identification and concentration, whether from relevant and reliable scientific information or from reasonable assumptions, be described and documented when environmental risk is involved.

   ACS, therefore, suggests the following additions be incorporated into Section 624, Principles for Risk Assessment:

   (h) When conducting environmental risk assessment involving substance-specific information based on *relevant and reliable scientific information*, the agency shall state how confident it is that the substances involved are (1) correctly identified and (2) that their concentration levels are correctly assessed. The basis for calculating those confidence levels shall also be provided.
   (i) When conducting environmental risk assessment involving substance-specific information based on *reasonable assumptions*, the agency shall state how confident it is that the substances involved are (1) correctly identified and (2) that their concentration levels are correctly assessed. The basis for selecting those confidence levels shall also be provided.

3. This bill's goal is to improve regulations. One challenge to improving the scientific basis of regulations is the gaps in knowledge about how to best assess certain risks. The American Chemica Society, therefore, recommends that toxicology and exposure assessment should be top priorities in risk assessment research.

   ACS strongly endorses the proposals in Section 628 (c)(1) and (2) for each agency to develop a strategy to meet its needs for research and training in risk assessment and cost-benefit analysis and for the Director of OIRA (Director) to engage a scientific institution to conduct research to assist comparative risk analysis and risk communication. However, the Society believes that useful research results will not be obtained in the limited time of approximately 1 year implied by the wording of Section 628 (c)(2)(B). ACS, therefore, suggests that the deadline for a report on the comparative risk research to the Director and to Congress in this Subsection be changed from 18 months to 24 months.

   Similarly, the Society underscores the need for research to develop a systematic comparison of significant risks, methodologies to compare dissimilar risks, and recommendations on the use of comparative risk analysis as a tool in determining priorities and allocation of agency resources. However, ACS believes that the suggested time of 18 months for this study is too short. The Society recommends that the deadline for a report to Congress in Section 629 (b)(2) be changed from 3 years to 42 months after enactment.

STATEMENT OF THE EDISON ELECTRIC INSTITUTE ON THE REGULATORY IMPROVEMENT ACT OF 1999 (S. 746)

The Edison Electric Institute (EEI) welcomes the opportunity to submit comments in support of the Regulatory Improvement Act of 1999 (S. 746). EEI is the association of the nation's shareholder-owned electric utilities, international affiliates and associate members, whose domestic members produce about three-quarters of the nation's electricity.

The electric utility industry is affected by a broad scope of federal and state statutes and regulations, and is one of the most regulated industries in this country. In 1995, EEI member companies spent more than $5.5 billion on compliance with federal environmental regulations alone. There are many additional health, safety, economic, and other regulations our industry must comply with on the federal, state, and local levels.

There is a continuing concern about the scientific credibility of the federal regulatory process, and the increasing costs to society to comply with environmental, health, and safety regulations. This concern is compounded by limited resources at all levels of government, which precludes effective and efficient regulation of all risks to society. Federal, state, and local governments, and small and large businesses, as well as taxpayers, continue to invest billions of dollars in a regulatory process whose primary mission is to protect the public and our environment.

There is no question that the system we have in place in the United States to protect the health and safety of our citizens is the best in the world. The United States has made substantial progress during the past 25 years in environmental protection and in improving overall health and safety. The quality of our air and water has improved dramatically, the dangers of lead poisoning in children has been greatly reduced, new pharmaceuticals have reduced disease and illness, and all forms of transportation are safer. We continue to lead healthier and longer lives due in large part to federal regulation.

Unfortunately, the current regulatory system has been recognized to have significant problems and flaws. Federal regulations are issued by 110 different agencies. Different agencies regulate the same hazard and require varying and sometimes conflicting approaches to mitigation and remediation, some

statutes require substances to be regulated and mandate compliance no matter what the cost; many human health regulations are based on incomplete or outdated science or even with no scientific basis at all. Indeed, many scientifically based regulations are centered more on politics than on science. This has resulted in an inefficient, complex, burdensome, and very expensive regulatory system.

Total federal regulatory costs have been estimated to be between $430 billion and $600 billion per year. This translates to about $6,000 per year that each family in America spends on regulatory compliance. The fastest growing area of regulation has been in environmental protection. According to the Environmental Protection Agency, state and local governments and business and industry currently spend more than $150 billion per year to control pollution and achieve federal environmental goals.

Over the past two decades, the increasing costs and burdens of federal regulations have led to calls from all sectors of society for the federal government to improve its regulatory processes. While federal regulatory agencies have played an important role in improving the environment and making our lives safer and healthier, they have needlessly burdened the management and operations of state and local governments, businesses, and the lives of private citizens.

While everyone agrees that the public and the environment need to be protected from real risks and hazards, there is a growing consensus that the federal regulatory program is not achieving this goal in an efficient and economical manner. It may not be excessive to spend $150 billion a year to protect the environment; however, that is a lot of money to be used inefficiently and inadequately. A comparison of several health and safety regulations ranked by cost per premature death averted shows the enormous range of between $100,000 to over $125 million in costs per hypothetical death averted. A study by the Harvard Center for Risk Analysis indicates that just by reallocating current regulatory spending in a smarter and more efficient manner, we could save 60,000 more lives a year.

A diverse group of public and private organizations and individual experts have concluded that we have a regulatory system that needs to be modernized and updated and made more flexible. In an attempt to inject credibility, efficiency, and economy into federal regulatory policy, a consensus of

risk professionals and economists recommends the expanded use of risk assessment, comparative risk analysis, and cost-benefit analysis to set regulatory priorities for environmental protection and lead to regulation of the real risks to society.

A mechanism needs to be established to ensure that new regulations are issued after the risks have been prioritized, after the costs and benefits are analyzed, and after greater participation in the process by the public and independent experts. In addition, federal regulatory agencies should adopt more flexibility in how regulatory standards and objectives are to be met. The current command-and-control regime is rigid, inflexible, and imposes excessive costs and paperwork burdens.

EEI and our members believe that the environment and health and safety of our employees, customers, and the public can be more effectively protected by focusing on federal and state regulatory programs and resources that achieve risk reduction of the greatest benefit to society. EEI also believes that regulations designed to protect the environment and human health should have a sound scientific basis. The risk assessments and cost-benefit analyses of proposed regulations should also be subject to independent peer review. EEI and its members support the use of risk assessment, cost-benefit analysis, and comparative risk analysis as fundamental tools to reform and improve the federal regulatory process.

We believe that S. 746 builds upon what already exists, drawing on such things as President Clinton's Executive Order 12866, Vice President Gore's "Reinventing Government" initiative, and recent laws such as the Unfunded Mandates Act and the Small Business Regulatory Enforcement Fairness Act.

It adds important new tools that we believe will help regulators do a better job. Specifically, 1) Comparative risk analysis and benefit/cost analysis will improve priority setting and help allocate resources to the most important regulatory issues, 2) Science-based risk assessments will strengthen the record for regulatory decisions, 3) Independent peer review will ensure that regulatory decisions will stand upon a foundation of the best science and the best benefit/cost analyses. We also believe that by opening the rulemaking process to bring in more public insight and information, S. 746 will improve the quality of the risk assessments and regulatory analyses that agencies conduct.

Taken together, we are convinced that the rules emerging from the regulatory process envisioned by S. 746 will enjoy broader public understanding and greater acceptance by those they impact. Ultimately, that will mean less litigation and faster implementation.

Though we are broadly supportive of the bill, we have specific comments and suggestions that we believe will further improve several provisions of the bill, consistent with the intent of its sponsors, without changing its fundamental scope and purpose.

1. Judicial Review

The Problem: In Alliance USA testimony presented before this Committee by Thomas A. Walton in the last Congress (September 1997 hearings on S. 981), we recommended clarification of the Judicial Review section of the legislation to remain faithful to the agreed-upon principle that the bill will not cut back on any judicial review, under the Administrative Procedure Act or otherwise, *presently available* for rules and for risk and cost-benefit analyses accompanying rules. Changes were made in section 627 in consultation with the Administration. However, the second sentence of section 627(e) appears potentially to undercut the ability to obtain arbitrary-or-capricious review of rules under section 706 of the APA.

The best that can be said for that sentence is that it is unclear. Apparently the drafters intend to enable a court to reverse a rule if the court determines that an inadequate cost-benefit analysis or risk assessment renders the rule arbitrary or capricious, but not if the agency simply fails to follow procedures imposed by S. 746. Yet, other than if the agency "fails to perform" the analysis—covered by the first sentence—the court may be powerless to remand even if it would have done so under the arbitrary-or-capricious standard in the absence of S. 746. That suggests that a party challenging a rule based upon a flawed regulatory analysis could be worse off after enactment of S. 746 than under existing law. We do not understand this to be the intention of either the sponsors of this bill or the Administration. We thus believe a clarifying amendment is in order.

The Solution: The Committee should consider amending § 627(e) as follows--

> (e) If an agency fails to perform the cost-benefit analysis, cost-benefit determination, or risk assessment, or to provide for peer review, a court may, giving due regard to ***the principle of*** prejudicial error, remand or invalidate the rule. ~~The adequacy of compliance with the specific requirements of this subchapter shall not otherwise be grounds for remanding or invalidating a rule under this subchapter.~~ If the court allows the rule to take effect ***or remain in effect***, the court shall, ***in the absence of unusual circumstances,*** order the agency to promptly perform such analysis, determination, or assessment, or provide for such peer review. ***Except as stated in this subsection, the inadequacy of an agency's compliance with the requirements of this subchapter shall not be a basis for remanding or invalidating a rule on the ground that the agency action was without observance of procedure required by law.***

In our proposal, the "unusual circumstances" clause benefits the agencies by recognizing that there may be cases where so much time has passed since the rule went into effect that, for example, requiring peer review would not provide any benefit.

2. Where Separate Review is Provided Under Existing Law

The Problem: The present language in section 627(d) might be read to limit the opportunity for judicial review of a risk assessment to review only at the time of the final rule; this works well when a rulemaking is involved. However, at least one court has reviewed a risk assessment (in the *Flue Cured Tobacco* case) in the absence of a rule, and there may be other examples of risk assessments being "final agency action" for the purposes of review under existing law. We do not believe it is the intention of this legislation to affect any pending case or the current standards applicable to judicial review in either direction.

The Solution: Since section 624(a)(1)(A)(ii) refers to a risk assessment "that is not the basis of a rule

making," three additional words should be added to section 627(d), as follows--

> (d) The cost-benefit analysis, cost-benefit determination under section 623(d), and any risk assessment required under this subchapter ***for a rule*** shall not be . . . .

Again, this is not intended to change current law or what we understand to be the intent of S. 746 in any way.

3 Savings Clause

The Problem: In responding to an Alliance USA suggestion in hearings on S. 981, the predecessor bill, the sponsors of the legislation inserted new language section 622(b) to preserve the right of judicial review of risk assessments, for example, under the Safe Drinking Water Act, the Pipeline Safety Act, and other laws where the statutes currently provide for greater or even full Administrative Procedure Act review of the required assessments. Unfortunately, the language "opportunity for judicial review made applicable under other statutes" preserves the standing, venue, and timing when the statute so specifies, but the "standard" (like "without observance of procedure required by law") and even the "opportunity" for APA review that may exist through silence in the other statutes are in danger of being superseded. We do not believe this result is intended.

The Solution: The following change in section 622(b) would clarify the intended objective of that section--

> "(b) Nothing in this subchapter shall . . . alter or modify (3) any opportunity for ***or standard governing*** judicial review ~~made applicable~~ ***available*** under other statutes."

4. Substitution Risk

The Problem: Evaluation of substitution risks is required as part of the regulatory analysis under section 623(b)(2)(C), but failure to include this required evaluation is unreviewable in court, since it is not a cost-benefit analysis, cost-benefit determination, risk assessment, or peer review as spelled out in section 627.

The Solution: The evaluation of substitution risks should be made part of the cost-benefit analysis; that analysis, if omitted, can cause remand or invalidation of the rule. Thus the evaluation required under section 623(b)(2)(C), which requires identification and evaluation of substitution risk to be part of the regulatory analysis, should be moved to become item (iv) under section 623(b)(2)(A), which is part of the cost-benefit analysis.

5. Threshold for Peer Review

The Problem: In last Congress's hearings on Regulatory Improvement, Alliance USA recommended that the peer review provisions of S. 981 apply to cost-benefit analyses. That change was made by the Committee, but in reaching agreement with the Administration the sponsors raised the threshold for peer review of cost-benefit analyses provided under section 625(a)(1) to $500,000,000. We believe that the threshold should be the same $100,000,000 as for risk assessments. In light of its personnel limitations, the Office of Information and Regulatory Affairs in OMB does not perform the level of review of cost-benefit analyses that the significance of these analyses demands; peer review can perform this function. Additionally, there will be greater incentive for agencies to improve the quality of the analyses if a peer review panel will be providing public comments.

The Solution: We propose that the threshold in section 625(a)(1) be lowered from $500,000,000 to $100,000,000

6. Sensitive Subpopulations

The Problem: In its mark-up on S. 981, the Committee adopted an amendment calling for evaluating each major rule's impact on "sensitive subpopulations." While we see this as well-intentioned, it is probably impossible for agencies to comply with that requirement in most cases, and thus we are uncertain of the provision's likely impact.

The Solution: We suggest either deleting section 623(b)(2)(A)(iv)(IV) or making sure that it is qualified by "where feasible."

EEI and its member companies advocate an open and transparent regulatory process based on the application of sound science, urge the benefits and costs of regulations to be explicitly considered, and encourage agencies to prioritize their activities. EEI believes these principles will allow the electric utility industry to focus limited resources on reducing environmental and human health risks while enhancing the health and safety of our employees, customers, and the public. We believe that S. 746, if enacted, would be a major step in achieving these principles.

Statement on S. 746
The Regulatory Improvement Act of 1999
Senate Committee on Government Affairs
April 22, 1999

The National Federation of Independent Business (NFIB) appreciates the opportunity to comment on the effect of regulations on small businesses and to offer our assessment of S. 746, the Regulatory Improvement Act of 1999.

The Importance of Regulatory Reform to Small Business

Unreasonable government regulations and the federal paperwork burden consistently rank as two of our members' top ten concerns in the NFIB Education Foundation study, Small Business Problems and Priorities. In fact, problems relating to government regulation are the fastest rising area of concern among our members.

In order to understand the full impact of regulations on small businesses, the committee must look at the composition of the business community as a whole. Despite what many Americans think, all business is not big business. Sixty percent of all employers in the United States have 4 employees or less, and 94 percent employ fewer than 50 employees. These figures illustrate a fact that is easily lost during debates on the impact of legislation and regulations -- that small business is the principal fuel for this nation's economic engine. Choking these businesses with overregulation and paperwork endangers our ability to protect and maintain economic growth nationwide.

How S. 746 Helps Small Business

S. 746 contains some very useful tools that, if adhered to by the agencies, can be used to reduce the burden of regulations on small businesses. NFIB supports provisions that:

* Provide for cost-benefit analyses of major rules and allow the analyses to become part of the rulemaking record.

* Disclose information about risks, including assumptions, estimates and comparable risk scenarios.

* Require peer review to be done independent of the agency program.

* Codifies the review procedure now conducted by the Office of Information and Regulatory Affairs (OIRA) and requires public disclosure of OIRA's review process.

The Need for Review of Rules

NFIB hopes that as the Committee considers this legislation further, it will look at other provisions that would ease the regulatory burden on small businesses. In particular, we hope the Committee reconsiders language that has been included in previous versions of the legislation that would strengthen the Regulatory Flexibility Act.

Many of the regulations and paperwork requirements that have frustrated small business owners come from laws that are outdated and need to be reviewed. In recognition of this problem, Congress passed the Regulatory Flexibility Act (RFA) in 1980. This law, which was strengthened in 1996, directs the federal agencies to assess the impact of any proposed major regulation on small businesses, consider alternative ways to achieve the regulatory objective and choose the least burdensome option or justify their reasons for not doing so. Section 610 of the RFA requires a review of regulations within ten years of adoption to insure that no subsequent significant cost impact on small businesses has occurred.

Unfortunately, many agencies have ignored section 610 and have taken no steps to mitigate the regulatory burden on small entities. NFIB supported the language in the Chairman's bill from the 105th Congress that strengthened section 610 by establishing firm review timetables for the agencies and allowing for public notice and comment on agency review plans. We urge you to include similar language in S. 746.

Opponents of a stronger section 610 have characterized this provision as "unworkable." If a federal agency finds it overly burdensome to review regulations, how can that same agency expect a small business owner to comply with all of its regulations? This provision only seeks to make existing law work -- and to require agencies to fulfill their current responsibilities.

In addition to S. 746, other legislation exists that would further ease the regulatory burden on small businesses. NFIB fully supports action on and passage of the Small Business Paperwork Reduction Act, the Mandates Information Act and the Regulatory Right to Know legislation. We urge your favorable consideration of these bills.

Conclusion

In the last few years, there have been notable achievements in regulatory reform: Unfunded Mandates Act, Paperwork Reduction Act, and the Small Business Regulatory Enforcement Fairness Act. Regulation remains a serious concern for small businesses, and one that we believe S. 746 continues to address.

As you move forward in the legislative process, we would ask that you consider adopting the strengthening amendments we have described. NFIB believes that they would provide agencies with a sounder basis for decision making by ensuring that Congress, the public and the agencies are better informed about why a regulatory decision was made, what alternatives were available, what data and analysis were used and what the economic impact will be.

April 20, 1999

SenatorThompson
Chariman, Senate Governmental Affairs Committee
523 Senate Dirksen Building
Washington DC 20510

Dear Mr. Thompson:

On behalf of Associated Builders and Contractors (ABC) and its more than 20,000 contractors, subcontractors, material suppliers, and related firms across the country I would like to express our support for legislation introduced by Senator Levin (D-MI) and yourself, S. 746, the Regulatory Improvement Act of 1999 and respectfully submit the following comments for the record.

Regulations by federal agencies are increasingly placing an unfair burden on America's construction businesses. In 1998 total regulatory costs were almost $737 billion dollars. Congress must inject some common sense into the federal rule making process by opening it to public scrutiny and making agencies accountable for results.

ABC believes this bi-partisan legislation that will apply cost/benefit analysis and comparative risk analysis to the rule making process; use science based risk assessments to help regulators set priorities; require an independent peer review on the science and cost benefit analysis performed on regulatory decisions encourage public participation in the risk assessment and regulatory analyses will be beneficial to the overburdened contractors across the country.

Sincerely,

Shane C. Downey
Washington Representative

1300 North Seventeenth Street ■ Rosslyn, Virginia 22209 ■ (703) 812-2000

STATEMENT OF D. LYNN JOHNSON
EASTMAN CHEMICAL COMPANY
ON S. 746

It is a pleasure to submit this statement supporting S. 746, the Regulatory Improvement Act of 1999, on behalf of Alliance USA – the Alliance for Understandable, Sensible, and Accountable Government Rules. My name is Lynn Johnson, and I serve as chairman of Alliance USA. I am also Vice President for Government Relations of Eastman Chemical Company, which is headquartered in Kingsport, Tennessee.

Ours is an ad hoc coalition of more than 1,000 companies of all sizes, trade and business associations representing everything from Fortune 500 companies to corner hardware stores, units of government, educational and other nonprofit institutions, and individuals. We embody the broad cross-section of America's private sector. Our common bond is a dedication to a better regulatory system. I have attached a current list of our members to this statement.

Alliance USA praises the bipartisan nature of this bill. We thank Senators Levin and Thompson for the hard work they have put in – during both the 105th Congress and the 106th – to build and maintain that support. I would point out that the bill before the Committee today is identical to the one the Clinton Administration endorsed, which is slightly modified from the bill a bipartisan majority of the Governmental Affairs Committee approved last year.

We believe S. 746 is good-government legislation that will help improve the nation's regulatory system by making it more understandable, sensible, and accountable. As our name makes clear, it is these three principles that are at the core of our Alliance. We believe:

> Understandable regulations will enjoy greater public acceptance.
>
> Sensible regulations will stand on a foundation of careful, thorough analysis.
>
> Accountable regulators will have greater confidence that they are addressing the most pressing issues sooner and faster, and that their work is more likely to withstand challenge.

Alliance USA members believe that consumers, workers, and all other Americans have a vital stake in improving the federal regulatory process. Good regulations – and there are many, such as those that took lead out of gasoline and improved the way we inspect meat – enhance the quality of life for all our people. Bad regulations – and, as we learn too often after the fact, there are many of those as well, such as mandatory asbestos removal, the ozone rule, and regulations setting Corporate Average Fuel Economy standards – complicate our lives, frustrating and confusing our citizens.

And, of course, all regulations impose costs. These costs take many forms, including higher prices, fewer choices, greater hassles, and slower action. Experts in government and the research community tell us the costs are substantial.

Professor Thomas Hopkins of the Rochester Institute of Technology testified before a House subcommittee last month that the total spending on regulatory compliance has climbed to just over $700 billion for 1999 – that is about 9 percent of our U.S. gross domestic product, or roughly $7,000 annually per family. This is simply a price that our nation cannot afford without evidence of equal or greater benefits.

Policy experts at leading universities – like Harvard and Duke – tell us that a better regulatory system would actually save more lives and while cutting the costs. Dr. John Graham, director of the respected Harvard Center for Risk Analysis, testified before this committee last year that we could save 60,000 additional lives each year at no additional cost if we shifted resources from wasteful to cost-effective programs. If we can, in fact, do that, common sense dictates that we should.

Environmental experts at research organizations have reinforced that message. Dr. Robert Repetto of the World Resources Institute has said, "we're not getting as much as we should for our expenditures on environmental protection." And Dr. Richard Morgenstern, a senior fellow at Resources for the Future who served as EPA's acting assistant administrator for policy from 1990 to 1993, has said the kinds of economic tools included in S. 746 will improve regulations by tightening their focus, reducing costs, and enhancing benefits.

The members of Alliance USA believe that S. 746 takes the right approach – a "what works" approach – to regulatory improvement. It builds upon what already exists, drawing on such things as President Clinton's Executive Order 12866, Vice President Gore's "Reinventing Government" initiative, and recent laws such as the Unfunded Mandates Act and the Small Business Regulatory Enforcement Fairness Act.

It adds important new tools that we believe will help regulators do a better job.

- Comparative risk analysis and benefit/cost analysis will improve priority setting and help allocate resources to the most important regulatory issues. As I mentioned a moment ago, experts believe that tools like these will save more lives at lower cost.

- Science-based risk assessments will strengthen the record for regulatory decisions. Dr. Milton Russell, another former EPA assistant administrator for policy, testified last year that well-executed risk assessments will document the reasons for regulatory decisions and enable new rules to move quickly to implementation.

- Independent peer review will ensure that regulatory decisions will stand upon a foundation of the best science and the best benefit/cost analyses. Dr. Bruce Alberts, president of the National Academy of Sciences, testified last year that peer review will ensure that regulators use the best science to make good policy.

We also believe that by opening the rulemaking process to bring in more public insight and information, S. 746 will improve the quality of the risk assessments and regulatory analyses that agencies conduct.

Taken together, we are convinced that the rules emerging from the regulatory process envisioned by S. 746 will enjoy broader public understanding and greater acceptance by those they impact. Ultimately, that will mean less litigation and faster implementation.

Another feature of S. 746 is that it maintains existing statutory authorities and allows agencies to function with the same statutory discretion they have always had, as it looks to the future. Agencies are free to make decisions within the same statutory framework that exists today, but they will be better equipped with good science, solid economic and risk analyses, and a better sense of the consequences of their actions. Members of Congress and the American public will have that same information, too.

As good as S. 746 is, the members of Alliance USA believe it is possible to improve it further. We ask the Committee to consider the suggestions that are appended to this testimony. They do not change the basic policies and objectives of the bill, but would make some of its provisions clearer and, in some ways, more true to those objectives.

Conclusion

In the final analysis, the debate surrounding S. 746 is not about *whether* to regulate, for we must regulate when it is in the nation's interest. Rather, the debate is about *how* to regulate better so that the public's interest is best served.

Dr. Morgenstern, the former EPA official I quoted earlier, has said the kinds of tools included in this legislation will "grease the wheels of democracy" by giving policymakers, legislators, and the public at large the information they need to think, deliberate, and decide. If that is the case, and I believe it is, then we are confident that S. 746 will foster better regulations in the future.

Alliance USA urges its early enactment.

PROPOSED MODIFICATIONS TO S. 746

This memorandum sets out, on behalf of Alliance USA, proposals to amend certain provisions of S. 746. Alliance USA does not believe any of these proposed changes offend the essential character of the legislation or the principles espoused by its supporters; our recommendations are intended to refine and clarify. However, without these changes, we fear that the legislation might be read in ways that could not only deprive the public of the intended benefits of the bill, but also undermine existing legislative authority.

1. Exclusion of Pesticides

The Problem: As introduced, S. 746 contains a carve-out in section 621(10)(j) that excludes from the definition of "rule" covered by the requirements of the legislation –

> a rule or agency action that authorizes or bars the introduction into or removal from commerce, or recognizes or cancels recognition of the marketable status, of a product under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq.) . . . .

The effect of this language is to exclude from the requirements for cost-benefit analysis, risk assessment, cost-benefit determinations, and peer review those FFDCA rules that are likely to have an annual effect on the economy of $100 million or more in reasonably quantifiable costs. The subject matter of rules excluded by this provision includes food additives, color additives, medical devices, and pesticides.

While exclusion from S. 746 of rulemakings relating to food and color additives and medical devices was recommended by the FDA and has not attracted concern on the part of the makers and users of these products, exclusion of pesticides from the requirement of cost-benefit analysis and assessment of substitution risks and reasonable alternatives has generated greater opposition. The need for greater, not diminished, analysis and transparency in this field is illustrated by the April 8, 1998, public memorandum from Vice President Gore to Agriculture Secretary Glickman and EPA Administrator Browner on implementation of the pesticide tolerance-setting provisions of the Food Quality Protection Act. The memorandum directed that implementation be consistent with sound, peer-reviewed science; be transparent to affected constituencies; provide a reasonable transition that includes creative, common-sense approaches; and be done in consultation with industry, the affected public, and other agencies and organizations.

The standards for developing regulations that set tolerances for pesticides and that may result in removal of a specific compound from the market are set under the FQPA. We do not propose to change these standards under the guise of regulatory improvement. More important, these standards would be neither changed nor superseded should EPA be required by S. 746 to develop, in addition to a risk assessment already required by the statute, a regulatory impact statement addressing the important cost-benefit, substitution risk, and cost-effectiveness.

The Solution: S. 746 should be amended to remove language excluding pesticide tolerance-setting rules from its definition of rules covered by the requirements of the legislation. This can be done by either deleting the entire exemption in section 621(10)(j) or by confining that exemption to rules adopted by the Food and Drug Administration.

2. Judicial Review

The Problem: In Alliance USA testimony presented before this Committee by Thomas A. Walton in the last Congress (September 1997 hearings on S. 981), we recommended clarification of the Judicial Review section of the legislation to remain faithful to the agreed-upon principle that the bill will not cut back on any judicial review, under the Administrative Procedure Act or otherwise, *presently available* for rules and for risk and cost-benefit analyses accompanying rules. Changes were made in section 627 in consultation with the Administration. However, the second sentence of section 627(e), appears potentially to undercut the ability to obtain arbitrary-or-capricious review of rules under section 706 of the APA.

The best that can be said for that sentence is that it is unclear. Apparently the drafters intend to enable a court to reverse a rule if the court determines that an inadequate cost-benefit analysis or risk assessment renders the rule arbitrary or capricious, but not if the agency simply fails to follow procedures imposed by S. 746. Yet, other than if the agency "fails to perform" the analysis - covered by the first sentence - the court may be powerless to remand even if it would have done so under the arbitrary-or-capricious standard in the absence of S. 746. That suggests that a party challenging a rule based upon a flawed regulatory analysis could be worse off after enactment of S. 746 than under existing law. We do not understand this to be the intention of either the sponsors of this bill or the Administration. We thus believe a clarifying amendment is in order.

The Solution: The Committee should consider amending § 627(e) as follows--

> (e) If an agency fails to perform the cost-benefit analysis, cost-benefit determination, or risk assessment, or to provide for peer review, a court may, giving due regard to ***the principle of*** prejudicial error, remand or invalidate the rule. ~~The adequacy of compliance with the specific requirements of this subchapter shall not otherwise be grounds for remanding or invalidating a rule under this subchapter.~~ If the court allows the rule to take effect ***or remain in effect***, the court shall, ***in the absence of unusual circumstances,*** order the agency to promptly perform such analysis, determination, or assessment, or provide for such peer review. ***Except as stated in this subsection, the inadequacy of an agency's compliance with the requirements of this subchapter shall not be a basis for remanding or invalidating a rule on the ground that the agency action was without observance of procedure required by law.***

In our proposal, the "unusual circumstances" clause benefits the agencies by recognizing that there may be cases where so much time has passed since the rule went into effect that, for example, requiring peer review would not provide any benefit.

3. Where Separate Review is Provided Under Existing Law

The Problem: The present language in section 627(d) might be read to limit the opportunity for judicial review of a risk assessment to review only at the time of the final rule; this works well when a rulemaking is involved. However, at least one court has reviewed a risk assessment (in the *Flue Cured Tobacco* case) in the absence of a rule, and there may be other examples of risk assessments being "final agency action" for the purposes of review under existing law. We do not believe it is the intention of this legislation to affect any pending case or the current standards applicable to judicial review in either direction.

The Solution: Since section 624(a)(1)(A)(ii) refers to a risk assessment "that is not the basis of a rule making," three additional words should be added to section 627(d), as follows--

> (d) The cost-benefit analysis, cost-benefit determination under section 623(d), and any risk assessment required under this subchapter ***for a rule*** shall not be . . . .

Again, this is not intended to change current law or what we understand to be the intent of S. 746 in any way.

4. Savings Clause

The Problem: In responding to an Alliance USA suggestion in hearings on S. 981, the predecessor bill, the sponsors of the legislation inserted new language section 622(b) to preserve the right of judicial review of risk assessments, for example, under the Safe Drinking Water Act, the Pipeline Safety Act, and other laws where the statutes currently provide for greater or even full Administrative Procedure Act review of the required assessments. Unfortunately, the language "opportunity for judicial review made applicable under other statutes" preserves the standing, venue, and timing when the statute so specifies, but the "standard" (like "without observance of procedure required by law") and even the "opportunity" for APA review that may exist through silence in the other statute are in danger of being superseded. We do not believe this result is intended.

The Solution: The following change in section 622(b) would clarify the intended objective of that section--

> "(b) Nothing in this subchapter shall . . . (3) alter or modify any opportunity for ***or standard governing*** judicial review ~~made applicable~~ ***available*** under other statutes."

5. Substitution Risk

The Problem: Evaluation of substitution risks is required as part of the regulatory analysis under section 623(b)(2)(C), but failure to include this required evaluation is unreviewable in court, since it is not a cost-benefit analysis, cost-benefit determination, risk assessment, or peer review as spelled out in section 627.

The Solution: The evaluation of substitution risks should be made part of the cost-benefit analysis; that analysis, if omitted, can cause remand or invalidation of the rule. Thus the evaluation required under section 623(b)(2)(C), which requires identification and evaluation of substitution risk to be part of the regulatory analysis, should be moved to become item (iv) under section 623(b)(2)(A), which is part of the cost-benefit analysis.

6. Threshold for Peer Review

The Problem: In last Congress's hearings on Regulatory Improvement, Alliance USA recommended that the peer review provisions of S. 981 apply to cost-benefit analyses. That change was made by the Committee, but in reaching agreement with the Administration the sponsors raised the threshold for peer review of cost-benefit analyses provided under section 625(a)(1) to $500,000,000. We believe that the threshold should be the same $100,000,000 as for risk assessments. In light of its personnel limitations, the Office of Information and Regulatory Affairs in OMB does not perform the level of review of cost-benefit analyses that the significance of these analyses demands; peer review can perform this function. Additionally, there will be greater incentive for agencies to improve the quality of the analyses if a peer review panel will be providing public comments.

The Solution: We propose that the threshold in section 625(a)(1) be lowered from $500,000,000 to 100,000,000.

7. Sensitive Subpopulations

The Problem: In its mark-up on S. 981, the Committee adopted an amendment calling for evaluating each major rule's impact on "sensitive subpopulations." While we see this as well-intentioned, it is probably impossible for agencies to comply with that requirement in most cases and thus are uncertain of the provision's likely impact.

The Solution: We suggest either deleting section 622(b)(2)(IV) or making sure that it is qualified by "where feasible."

HEALTH PHYSICS SOCIETY

Specialists in Radiation Safety

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Statement of the Health Physics Society

On

The Regulatory Improvement Act of 1999 (S. 746)

for the record to the

Senate Committee on Governmental Affairs Hearing

by

Keith H. Dinger, President
Health Physics Society

April 21, 1999

Statement of the Health Physics Society
On
The Regulatory Improvement Act of 1999 (S. 746)

The Health Physics Society is a scientific organization of professionals whose mission is to promote the practice of radiation safety, thereby protecting human health and the environment. Today its nearly 6,000 members represent all scientific and technical areas related to radiation safety including academia, government, medicine, research and development, analytical services, department of defense, consulting, and industry. The Society is chartered in the United States as an independent non-profit scientific organization, and, as such, is not affiliated with any government or industrial organization or private entity. Society activities include encouraging research in radiation science, developing standards, and disseminating radiation safety information.

The Health Physics Society strongly supports the need for improvement of the regulatory process to ensure there is judicious and equitable expenditure of limited public resources for protection of the environment, improvement of public health, and ensuring worker safety. The "Regulatory Improvement Act of 1999," S. 746, provides for improvements of the current regulatory process, including improved use of scientific and economic analysis in developing regulations, independent peer review of the analysis, and incorporation of comparative risk analysis for setting priorities for the reduction of risks to human health, for safety, and for protecting the environment. **Therefore, we strongly support the passage of S. 746.**

One example of the need for a scientifically conducted economic analysis of regulatory actions is provided by the Uranium Mill Tailings Radiation Control Act (UMTRCA) enacted in 1978. This legislation authorized the federal government to conduct remedial action at 20 inactive uranium mill sites and associated vicinity properties. The Department of Energy has now completed this project, at a total cost of $1.45 billion. An analysis of the cost-effectiveness of the UMTRCA project appeared in the recent issue of *Health Physics*, the Official Journal of the Health Physics Society (Vol. 76, No. 5, pages 544 - 546, May 1999). This analysis demonstrates that five sites and all vicinity properties result in a calculated cost/hypothetical-death prevented that is within a range often accepted in cost/benefit analysis for public health policy (i.e., $ 0.24 million to $ 2.4 million per hypothetical death). However, the analysis also demonstrates that 15 of the sites, representing an expenditure of $570 million, result in a calculated cost/hypothetical-death prevented that is outside the range of a reasonable value which would justify taking action for public health purposes (i.e., $9.7 million to $ 18,000 million per hypothetical death).

A peer reviewed risk assessment using the best available scientific information, such as that referenced above, would likely identify the expenditure of the $570 million for these 15 sites does not represent a judicious expenditure of public resources for public or environmental health improvement. A comparative risk analysis would identify many other actions that would provide a much greater public or environmental health return for the same amount money.

Conclusion: The non-judicious appropriation of public resources for public and environmental health protection can result in more harm than good. Since regulatory programs that provide the important benefit of improving the environment, worker safety, and public health can impose a significant drain on limited public resources, it is necessary to have a regulatory framework that evaluates these expenditures and ensures the public is receiving an appropriate benefit for regulatory program expenses. The "Regulatory Improvement Act of 1999"(S.746) provides such a framework. **Therefore, the Health Physics Society supports passage of S. 746.**

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The Health Physics Society, formed in 1956, is a scientific organization of professionals who specialize in radiation safety. Its mission is safeguarding of human health and the environment from potentially harmful exposures to radiation or radioactive materials in both public and private activities. Today its nearly 6,000 members represent all scientific and technical areas related to radiation safety including academia, government, medicine, research and development, analytical services, consulting, and industry in all 50 states and the District of Columbia. The Society is chartered in the United States as an independent non-profit scientific organization, and, as such, is not affiliated with any government or industrial organization or private entity. Its headquarters are in McLean, Virginia. The Society is dedicated to the development, dissemination, and application of scientific and practical knowledge regarding radiation safety and control.

Expertise of the members of the Health Physics Society:
Members of the Health Physics Society work in a variety of professional areas including research, industry, education, environmental protection, governmental activities, regulation, enforcement, and medicine.

Research - Health Physics researchers investigate principles by which radiation interacts with matter and living systems. The field also involves study of environmental transport of radioactivity and the effects of radiation on biological organisms. Research is used in many ways, ranging from designing radiation detection instrumentation to health risk assessments necessary for establishing radiation protection standards.

Industry - Applied Health Physicists draw on their technical knowledge to advise, recommend, and implement methods and appropriate equipment for use in industrial work involving radionuclides and radiation. Health Physicists oversee radiation safety activities and manage radiation control programs.

Education - Educational Health Physicists provide education and training for future health physicists, radiation workers, and the general public on radiation safety and methods in use for safeguarding human health and the environment. They include faculty members at major universities in the United States, as well as those whose jobs include administration of training programs and teaching. Many universities have specific courses of study and offer degrees in Health Physics and related fields that include radiation safety.

Government - Health Physicists working in governmental activities, regulation, and enforcement have experience and knowledge of potential radiation hazards. They are involved with establishing guidelines for radiation control which benefit both workers and the public. Society members are employed by the Department of Defense, Environmental Protection Agency, the Nuclear Regulatory Commission, the Department of Energy, the National Institutes of Health, various other Federal agencies, and radiation control agencies in all 50 states.

Medicine - Radiation is used in every modern hospital today to diagnose or treat disease. Medical Health Physicists ensure the safety of patients and staff who are exposed to radiation sources used in diagnosis or therapy as well as insuring the quality of radiation machines and instrumentation. In addition, medical Health Physicists teach radiation safety, physics, and biology to medical personnel.

The Health Physics Society is a professional resource at the disposal of the Congress and the Administration as needs arise for objective advice regarding pertinent radiation safety issues. The Society looks forward to being of assistance in this important area of science and governmental policy.

Statement of the
Chemical Manufacturers Association
on S.746 - The Regulatory Improvement Act of 1999
Before the Senate Committee on Governmental Affairs

April 21, 1999

Introduction

The Chemical Manufacturers Association (CMA) is pleased to submit this statement on S.746 - the Regulatory Improvement Act of 1999. CMA strongly supports the goals of S.746 because they will --

- improve the quality of the scientific/economic information and related analyses upon which major agency rules are based;
- promote the public's "right to know" about the costs and benefits of regulations and the scientific and economic underpinnings of major agency rules;
- improve risk-based priority setting and comparative risk communication at Federal agencies; and
- enhance Presidential oversight and coordination of Federal regulatory actions.

CMA views S.746 as an important first step in achieving a more responsible and responsive Federal regulatory system. Accordingly, we wish to express our appreciation to Senator Thompson (R-TN), Senator Levin (D-MI), and others who have labored long and hard -- in a bipartisan manner -- to craft compromise legislation and bring it before the Committee. At the same time, we believe that some changes to the bill are necessary to assure that it effectively achieves its goals of greater accountability and transparency in the rulemaking process. As noted in the executive summary, CMA believes that the portion of the bill which excludes certain decisions under the Federal Food, Drug and Cosmetic Act from the scrutiny required by S. 746, must be deleted.

CMA is a nonprofit trade association whose member companies represent more than 90 percent of the productive capacity for basic industrial chemicals in the United States. The chemical industry now provides one million jobs for American workers, an overall employment

level that has been maintained over the past decade, even though the U.S. chemical industry has changed dramatically to enhance productivity and remain competitive in domestic and world markets. Today, the chemical industry is the leading U.S. exporter. Chemical exports in 1998 totaled $68.0 billion, over 10 cents out of every dollar of U.S. goods exported in that year, and produced a net trade surplus of $13.4 billion. This continues a more than 70 year uninterrupted history of US chemical industry trade surpluses. Indeed, during the 10 years ending in 1998, the industry rang up trade surpluses totaling $169 billion.

The chemical industry wants to remain a productive and competitive sector of the American economy that can continue to produce a myriad of products that enhance our quality of life, provide good manufacturing jobs, and contribute to the expansion of U.S. merchandise exports. At the same time, as evidenced by the Guiding Principles and Codes of Management Practices that have been adopted under CMA's Responsible Care® initiative, CMA members are committed to managing chemicals responsibly throughout a product's life cycle, and they place a high priority on protecting the health and safety of their employees, their customers, the general public, and the environment. CMA is proud of the fact that worker injury and illness rates in the chemical industry are less than half the U.S. manufacturing average.

CMA's commitment to the safe management of chemicals was most recently evidenced by the strong response that individual CMA members and consortia of CMA companies have made to EPA's High Production Volume (HPV) Chemical Challenge program being implemented as part of Vice President Gore's expanded chemical right-to-know initiative. The HPV Challenge and other research and testing initiatives will involve expenditures of roughly $1.2 billion by the U.S. chemical industry over the next five years.

CMA recognizes that regulatory programs play an important role in protecting human health, safety, and the environment. At the same time, we believe there is considerable room for improvement in the regulatory process. In October 1993, when he issued his Executive Order on Regulatory Planning and Review, President Clinton said the "American people deserve a regulatory system that works for them not against them; a regulatory system that protects and improves their health, safety, environment and well-being and improves the performance of the economy without imposing unacceptable or reasonable costs on society." This system, the President said, should produce "regulations that are effective, consistent, sensible and understandable." The country, the President said then, does "not have such a regulatory system

today."[1] Despite his efforts and those of the Vice President -- as reflected in various "regulatory reinvention" initiatives undertaken during the course of the past five and a half years--the country still does not have such a system.

The Environmental Protection Agency, for example, has fallen far short of its reinvention goals. In 1994, the General Accounting Office (GAO) found that the Common Sense Initiative (CSI), which the agency has said is the "centerpiece" of its reinvention efforts, had not delivered "the types of changes in the existing approach to environmental management that EPA suggested."[2] The CSI was launched in 1994 as an EPA partnership program with six industrial sectors whose goal was to simultaneously examine all air, water, land, and toxics rules applicable to those sectors. And the National Academy of Public Administration (NAPA), following up on its landmark 1995 study of the environmental protection system, concluded in September 1997 that "EPA's reinvention experiments have not yet produced major changes in EPA's core programs." Reinvention, NAPA said, "is operating at the margins."[3] While reinvention efforts at EPA continue to proliferate, the extent to which reinvention has succeeded remains debatable. Thus, the Common Sense Initiative has been terminated.[4] An analysis presented to EPA's National Advisory Committee for Environmental Policy and Technology earlier this month concluded that EPA has made little progress in addressing broad regulatory changes as a result of the CSI program.[5] Moreover, on-going reinvention efforts seem to be focusing on matters other than improvement in the regulatory process.[6] Thus, if we are to achieve the President's goals for an effective and sensible regulatory system that works for the American people, the Administration and the regulatory agencies it directs need help. S.746 would provide that help.

S.746 is not designed to eliminate the fundamental structural obstacles that hinder the reinvention efforts of EPA and other agencies. Rather, S.746 will give agencies tools they can use to improve the quality of those rulemaking decisions that have the most substantial

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[1] 58 Fed. Reg. 51735, October 4, 1993.

[2] "Regulatory Reinvention: EPA's Common Sense Initiative Needs an Improved Operating Framework and Progress Measures," U.S. General Accounting Office, report to Congress, July 1994, p. 5. (GAO report to Congress.)

[3] "Resolving the Environmental Paradox: An Agenda for Congress, EPA, and the States," National Academy of Public Administration, September 1997, p. 1.

[4] See 63 Fed. Reg. 66806 (December 3, 1998) (announcing the final meeting of the Common Sense Initiative Council).

[5] See Bruninga, S., "CSI Successes Not Being Integrated Into Core EPA Programs," Daily Environment Report, (BNA, Inc.) April 16, 1999.

consequences for our economy and our society. At the same time, S.746 would help ensure that the public is more fully informed about the costs and benefits of agency actions and about the informational bases, policy choices, and scientific and technical assumptions that serve as the underpinnings for agency decisions. These changes represent a critical step toward improving the overall quality of the regulatory system and the performance and accountability of the agencies that manage the system. Importantly, S.746 will accomplish this without disturbing the existing substantive criteria for agency rulemaking.

The essence of what the legislation would accomplish can be summarized as follows:

- S.746 will promote the public's right to know about major agency decisions that may have a significant impact on their lives. The bill will promote right-to-know objectives in several ways:
  - It will make the regulatory decision-making process more transparent.
  - It will make it easier for more Americans to participate meaningfully in the regulatory process -- with a better understanding of (1) the information on which the agency is relying, (2) the reasons for the scientific, technical, and policy choices the agency is making, and (3) the impacts, both positive and negative, that the rule under consideration is likely to have.
  - It will give the public and Congress information they need to more easily determine for themselves the justification for – and the impact of – major rulemaking decisions and to assess the advantages and disadvantages of alternative solutions to the problems being addressed.
- S.746 will improve the quality of the information and analyses the government uses to make regulatory decisions.
- S.746 will improve the quality and consistency of agency risk assessments and analytical procedures. At the same time, the bill's requirement for independent peer review of risk assessments underlying major rules will serve as an important check on the soundness of an agency's evaluation of complex scientific and technical issues. The credibility of agency assessments will be enhanced by endorsement and/or incorporation of changes made by independent peer review panels.
- S.746 will allow agencies to make better use of their resources through the setting of risk-based priorities.
- S.746 will strengthen presidential oversight, coordination and management of federal regulatory actions.

[6] See, *e.g.*, 64 Fed. Reg. 13187 (March 17, 1999); 64 Fed. Reg. 15159 (March 30, 1999).

- As a result of the foregoing, S.746 will improve the credibility of regulatory decisions and enhance public confidence in the regulatory process and in the regulations that emerge from that process.

CMA supports these goals, in fact, legislation embracing these principles has become a matter of usage.

During the next two to five years an unprecedented amount of new information about the health effects of chemicals will be generated and made available to agencies and the public. This information, principally raw results from laboratory tests but also more advanced fundamental research data, will be the product of a number of public and private initiatives, including the following:

- **Screening and Testing for Endocrine Effects:** This EPA-mandated program to screen and test some 15,000 chemicals for their potential to affect the endocrine system could cost industry as much as $500 million.

- **High Production Volume (HPV) Chemicals:** CMA and other industry trade associations have voluntarily agreed, in conjunction with EPA and the Environmental Defense Fund (EDF), to a framework for obtaining a base set of screening test data and other information on 2,800 High Production Volume (HPV) chemicals over the next five years. An internet based tracking system will allow the public to view commitments to test, monitor progress, and examine test plans. Test results will be made publicly available. The costs of the testing, which will be completed by 2004, are estimated to be around $500 million.

- **Testing for Particularized Effects on Children:** Another program still being developed under the auspices of EPA will require testing of potentially thousands of chemicals for particularized effects on children. The ultimate costs of this program are still unknown.

- **The Chemical Industry's Long-range Research Initiative:** Finally, our industry has committed to undertaking basic research on the health effects of chemicals in a long-range program coordinated with our counterparts elsewhere in the world. That program will involve expenditures of $22.5-$25 million per year over the next five years.

All of these data – to be created at considerable cost -- potentially will be critically important to making informed decisions regarding protection of human health and the environment. However, their value really depends on having the best possible framework in place to understand public health and environmental implications. S. 746 would help provide that framework -- by establishing sound principles for conducting risk assessments that use the best

scientific data, by requiring peer review of risk assessments where the economic stakes are high, and by putting the information generated under these research initiatives in proper context through the use of comparative risk analyses.

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In the pages that follow, we want to explain in more detail why the essential elements of S.746 are needed and what they would accomplish.

I. Why Is S.746 Needed?

A number of credible studies and reports issued during the last decade have pointed to the need to reform the regulatory process. One of these is the 1997 Final Report of the President's Commission on Risk Assessment and Risk Management. In that Report, the Commission observed: "Federal regulatory agencies are confronted with many problems and issues related to health and environmental protection, but have limited time and resources for action. The risks associated with the problems and the resources available to act on them are often misaligned."[7] The result of this misalignment, a study conducted in 1995 by the World Resources Institute concluded, "is that we're not getting as much as we should for our expenditures on environmental protection."[8] Instead, as a blue ribbon panel of the Carnegie Commission pointed out in 1993, by setting priorities on a "chemical-of-the-month" basis, the nation winds up overregulating some hazards, underregulating others, and reducing agency credibility.[9]

The consequences of these problems are significant. According to the Office of Management and Budget's most recent estimate, the costs of health, safety, and environmental regulation are in the range of $170 billion to $224 billion per year – roughly 2 percent of Gross Domestic Product.[10] And that figure is rising every year. Further, as a distinguished panel of economists (including Nobel laureate Kenneth J. Arrow of Stanford University) has pointed out,

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[7] "Risk Assessment and Risk Management in Regulatory Decision-Making," President's Commission on Risk Assessment and Risk Management, final report, 1997, Vol. 2, p. 46. (Risk Assessment Commission Report.)

[8] Repetto, "Jobs, Competitiveness, and Environmental Regulations: What Are the Real Issues," 1995.

[9] "Risk and the Environment: Improving Regulatory Decision-Making," Carnegie Commission on Science, Technology and Government, June 1993, p. 73.

[10] "Draft Report to Congress on the Costs and Benefits of Federal Regulations," 63 Fed. Reg. 44034, 44035 (August 17, 1998).

given the magnitude of environmental regulatory costs, "a reallocation of expenditures on environmental, health, and safety regulations has the potential to save significant numbers of lives while using fewer resources."[11] For that reason, Dr. Arrow and his colleagues urged Congress to require Federal agencies "to consider benefits and costs in formulating their regulatory priorities."[12]

That the regulatory system, in the words of Supreme Court Justice Stephen Breyer, "badly prioritizes the health and environmental risks we face,"[13] is not the only problem requiring a legislative fix. In the view of CMA members, there also are major shortcomings in the way health, safety, and environmental regulations are developed, structured, and implemented. In particular:

- When Federal agencies conduct risk assessments, the analyses tend to be unrealistic, overly conservative, and reflective of unstated and unexplained policy choices or default assumptions.

- In many cases, government decision makers and the public are given inaccurate descriptions of health and environmental risks. Usually, agency officials believe they are addressing larger risks than is actually the case. And the public many times is uncertain about what the agency is purporting to protect them against, or what the cost of that protection is. Congress, too, is a victim of this situation. Inaccurate risk characterizations make it difficult for oversight committees to evaluate the agency's performance or to determine what the agency is actually accomplishing.

- In most cases, the scientific and technical assessments on which regulations are based are not subjected to independent external peer review. As a result, the scientific and technical underpinnings of agency actions that may have significant social and economic consequences often are not adequately tested. Consequently, the technical foundation for agency decisions are not seen as credible.

- The economic consequences (as well as the other consequences) of agency rules frequently are not evaluated or discussed adequately.

- Some environmental regulations impose exceedingly high costs but achieve incremental environmental or health benefits that are uncertain at best.

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[11] "Is There a Role for Benefit-Cost Analysis in Environmental Health and Safety Regulations?" by Kenneth J. Arrow, et al., Science, April 12, 1996.

[12] Ibid.

[13] Stephen Breyer, testimony before the Committee on Energy and Natural Resources, United States Senate, November 9, 1993, p. 2.

- Agency rules tend to be inflexible, reflecting a penchant for the command-and-control approach to regulation. Among other things, this produces rules that are far less cost-effective than they could be. It also frequently precludes the adoption of more modern environmental management practices that not only would be more effective (while providing the same level of benefits), but also would cost less.[14]

- Frequently, alternatives to proposed regulatory actions do not receive the attention they deserve.

- Finally, the process by which agencies conduct hazard evaluations and risk assessments is not as open – not as "transparent" – as it either could be or should be.

Because of these significant flaws, CMA believes there are some regulations that fall far short of delivering health, safety, and environmental benefits that are reasonably related to their costs. Moreover, Federal regulations rarely are structured so as to give states and the regulated community maximum flexibility to achieve the rulemaking objectives in the most cost-effective manner. Furthermore, the bases for – and the impacts of – these regulations often are not fully understood by the public, by Congressional oversight committees, or even by the agency decision makers themselves. In addition, many agency rules focus on issues that are relatively less significant than other public health and environmental challenges.

S.746 alone will not provide all the improvements in the regulatory process that are necessary. However, the legislation will help agencies develop regulations in what Vice President Gore describes as "the right way -- regulating only when necessary and tailoring regulations to achieve their purpose in the least costly manner."[15] As stated in Section 2 of the bill, S.746 will help achieve this goal by "[i]mproving the ability of Federal agencies to use scientific and economic analysis in developing regulations," thereby yielding "increased benefits and more effective protections while minimizing costs." Moreover, to paraphrase Vice President Gore, S.746 will help ensure that agencies "carefully analyz[e] the likely effects of various alternatives" and make their regulations "as flexible as possible."[16] In addition, the bill explicitly recognizes and responds to the public's "right to know about the costs and benefits of regulations, the risks addressed, the risks reduced, and the quality of scientific and economic

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[14] As the Progressive Policy Institute has observed, command-and-control regulations "have begun to reveal many of the same limitations that led to the collapse of command-and-control *economies* around the globe. They can be inefficient; they hamper innovation in pollution control methods; and they ignore important differences among individuals, firms, and regions." "Mandate for Change," by W. Marshall and M. Schram, editors, Progressive Policy Institute, 1993, p. 197.

[15] The Regulatory Plan, 63 Fed. Reg. 61203 (November 9, 1998).

[16] *Ibid.*

analysis used to support decisions."[17] All of this, as the Vice President points out, "is vital to creating a government that works better and costs less" and that provides the American people "more benefits with fewer burdens."[18]

II. What S.746 Would Accomplish

Building on regulatory analysis initiatives that have been implemented by the last five administrations and on the more narrowly focused legislative actions taken in the recent Congresses, S.746 would improve the regulatory process in a number of ways. The most important of these are described below.

Regulatory Analysis. Executive Order 12866 already requires executive branch agencies to assess and quantify, to the extent feasible, the costs and benefits of their major rules and to consider alternative ways to achieve the regulatory objective. The Executive Order also directs agencies to "design regulations in the most cost-effective manner" and, subject to any constraints of the underlying enabling statutes, to adopt a rule "only upon a reasoned determination that the benefits of the intended rule justify the costs." S.746 will systematize and codify these regulatory analysis requirements for "major rules," will improve the quality of such analyses, and will make them more transparent, understandable, and consistent across agency programs. At the same time, without establishing mandatory decisional criteria, it would force agency policymakers to focus in a more rigorous way on the following questions:

- Is the rule likely to provide benefits that justify its costs?
- Will the rule achieve the rulemaking objectives more cost-effectively or with greater net benefits than other alternatives that the agency has authority to implement?
- Can the rulemaking objectives be achieved in a way that relies more on incentives and market forces and provides greater flexibility to regulated entities than is true under a traditional "command-and-control" approach?

These analytical improvements should lead to better agency decisions that are more readily accepted by those who must comply with (and those who must pay for) major agency rules. At the same time, S.746's regulatory analysis requirements for "major rules"

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[17] S.746, Section 2(6).
[18] The Regulatory Plan, 63 Fed. Reg. 61203 (November 9, 1998).

(including the cost-benefit and cost-effectiveness determinations/explanations) would enhance the public's right to know about important government decisions. Under S.746, the public would be given better, more complete, and more understandable information about the problem being addressed, alternative ways to remedy the problem, the information on which the agency placed substantial reliance in the rulemaking, the expected benefits of the agency's action, and the costs of the rule at issue. And, when an agency chooses to adopt a major rule that is not cost-justified or cost-effective, the public would be told why the agency made that decision.

Risk Assessment. S.746 would require agencies to apply a set of basic principles in conducting risk assessments for all proposed and final major rules whose primary purpose is to address health, safety, or environmental risk. These principles are designed to enhance the quality and scientific rigor of risk assessments, to promote more rational, better informed decisionmaking, and to make risk assessments more meaningful and understandable to agency policymakers and to the public at large. For example, section 624(g) requires that, where appropriate information is reasonably available, agencies must compare the risk being analyzed in the rulemaking to reasonably comparable risks familiar to and routinely encountered by the general public. As the Commission on Risk Assessment and Risk Management points out, "[i]t is logical and reasonable for people to request [such] comparisons [and] for Congress to incorporate mandates for risk comparisons in legislation."[19] In addition to improving the risk assessment process in individual cases, the principles established in S.746 will promote greater inter-agency and inter-program consistency in risk assessment practices and formats.

As in the case of the regulatory analysis requirements, the risk assessment provisions of S.746 serve an important "right-to-know" function. Risk assessments often depend on assumptions or "science policy" choices to bridge gaps in scientific knowledge or available data, and different assumptions or policy choices can produce dramatically different estimates of risk. If the public is to understand the true import of a risk assessment, the assumptions and "science policy" choices made by the agency must be fully disclosed and clearly explained, and the impact they have on the risk assessment must be made clear. Otherwise, the public's right to know and understand the bases for agency actions that can have a major impact on their lives will be frustrated. S.746 would assure that such "full disclosure" will be a hallmark of risk assessments for major rules.

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[19] Risk Assessment Commission Report at 41.

Peer Review. S.746 would require agencies to provide for peer review of risk assessments that form the basis of major rules and of cost-benefit analyses for rules that the OMB Director reasonably anticipates are likely to have an annual effect on the economy of $500,000,000 or more. As the Commission on Risk Assessment and Risk Management points out, this should "enhance the credibility of agency decisions and positions and . . . improve their technical quality."[20] Peer review will assume special importance in the years ahead as the results of the chemical industry's five-year $1.2 billion research programs on chemical toxicity and exposure-related issues become available for use in agency rulemakings. The peer review provisions of S.746 also would promote the public's right to know about the basis for (and the cogency of) agency decisions on important scientific and technical issues, since the bill requires that peer reviewer comments and the agency's response to those comments be placed in the rulemaking record. In addition to these benefits, an independent peer review process, as Robert Hahn and Robert Litan of the Brookings Institution pointed out to this Committee last year, may actually expedite the implementation of controversial health, safety, or environmental regulations because "rules that are supported by well-done regulatory analyses that have been peer reviewed are much more likely to withstand . . . opposition, either in Congress . . . or in the courts."

Consistency/Compatibility of Cost-Benefit Analyses and Risk Assessments. S.746 would require OMB, in consultation with the Office of Science and Technology Policy and the Council of Economic Advisors, to develop guidelines for cost-benefit analyses and risk assessments. Individual agencies, in turn, would have to adopt their own more detailed risk assessment guidelines consistent with the government-wide guidance issued by OMB. Not only will this improve the quality of individual cost-benefit analyses and risk assessments, it also will promote greater consistency in analytical techniques, procedures, and formats both within and among Federal agencies dealing with health, safety, and environmental issues. As a result, it will be possible to make more meaningful and insightful comparisons of different agency rules and programs.

Comparative Risk Analysis Methodologies, Evaluations, and Communication. S.746 also would require OMB to arrange for research and studies into the conduct of comparative risk analysis, the communication of risk information, and the incorporation of risk assessment results into cost-benefit analyses. Under a separate provision, an accredited scientific

institution would conduct a systematic comparison of health, safety, and environmental risks and would develop methodologies and guidance for comparing such risks and determining how to set resource allocation priorities for the reduction of risks to human health, safety, and the environment. This would be an important step forward in the effort to end the "misalignment" of risks and resources that has been decried by so many expert groups and students of the regulatory process over the years.[21] The information generated in these studies would allow both Congress and the regulatory agencies to set more rational risk-based priorities and to focus resources on the most serious health, safety, and environmental risks, so that we can maximize the risk reduction benefits flowing from our enormous expenditures in these areas. To quote last year's testimony of Robert Hahn and Robert Litan, by setting priorities on the basis of a comparative risk study, we can "save more lives [possibly as many as 60,000 per year] at less cost."

Presidential Oversight of Regulatory Actions. Finally, S.746 would codify and establish certain ground rules for Presidential oversight and management of the regulatory activities of Federal agencies. OMB's role in the regulatory review and planning process would be made subject to specific guidelines on communication, public disclosure, and related matters. This should improve coordination among agencies -- particularly where a matter falls within overlapping spheres of authority (*e.g.*, OSHA's Process Safety Management Standard and EPA's Chemical Accident Prevention Rule) -- while enhancing public confidence in the openness of the regulatory review process.

III. Suggestions for Improving S.746

As discussed above, S.746 would improve the regulatory process in a number of important respects. We believe, however, that there are technical changes which will enable the Committee to provide greater assurance that improvements in regulatory decisionmaking will be realized. As noted previously, we also believe one important substantive change must be made, that is, to extend the bill's benefits to decisions affecting the pesticide industry. Our proposals in this regard are as follows.

Exclusion of Rules Under the Federal Food, Drug, and Cosmetic Act

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[20] See Risk Assessment Commission Report at 103.
[21] See Risk Assessment Commission Report at 46.

As discussed above, one of the most important functions of S.746 is to ensure that each "major rule" dealing with health, safety, and environmental protection undergoes a rigorous regulatory analysis and is supported by a risk assessment that has been conducted in accordance with specified principles and subjected to independent peer review. These requirements are intended to ensure that all major rules that address health, safety, or environmental risk will reflect a scientific and economic analysis that is of high quality and consistency. Any statutory exception to these requirements should have a logical and persuasive justification. Section 621(10)(J) lacks such a justification.

Section 621(10)(J) excludes from the definition of "rule" (and, therefore, from coverage under the regulatory analysis, risk assessment, and peer review provisions of the bill) rules promulgated under the Federal Food, Drug and Cosmetic Act that authorize or bar the introduction into or removal from commerce of a product -- or that recognize or cancel recognition of a product's marketable status. Rules potentially affected by this exclusion include those that determine whether food additives, color additives, medical devices, and pesticides can be sold in commerce.

When a rule of this type has an annual effect on the economy of $100,000,000 or more in reasonably quantifiable costs, we see no logical reason why it should be exempted from the regulatory analysis, risk assessment, and peer review requirements of S.746. Indeed, such rules -- particularly those dealing with pesticides -- are likely to present some of the most challenging questions regarding substitution risks of any rule dealing with health, safety, or the environment. Section 621(10)(J) should be deleted.

Judicial Review

Consistent with what we understand to be the intent of its drafters and sponsors, S.746 should preserve all rights and opportunities for judicial review of agency action that currently are available under other provisions of law. While it may limit judicial review of agency compliance with some of the new requirements it establishes for the promulgation of major rules, the bill should not create a "supermandate" that overrides existing opportunities for judicial review or the standards of review that apply under other statutes. From that perspective, we offer the following observations on Section 627 under the new legislation.

Section 627 sets strict limitations on judicial review of agency compliance with the provisions of S.746. In the past, we have questioned both the rationale underlying section 627's severe restrictions on judicial review and the way in which the provision is formulated. While we still have those concerns, we understand that section 627 reflects a carefully considered legislative compromise, and we do not propose to upset that compromise. We do believe, however, that a few technical clarifications should be made in order to reduce confusion and to reflect more accurately what we understand to be the agreement that has been reached with respect to judicial review.

(1) The first sentence of subsection 627(d) states that "any risk assessment required under this subchapter shall not be subject to judicial review separate from review of the final rule to which such . . . assessment applies." This statutory "ripeness" provision makes sense for risk assessments that are performed in connection with a major rule as required by section 624(a)(1)(A)(i). However, it makes no sense for a risk assessment that is unrelated to a rulemaking, *i.e.*, a free-standing risk assessment of the type described in section 624(a)(1)(A)(ii). Since there will not be a final rule to which such a risk assessment applies, it should not be subject to the final rule "ripeness" provision set forth in the first sentence of subsection 627(d). Whether such a risk assessment is reviewable in court at all -- and, if so, at what time -- are questions that can and should be answered independently of S.746, since the bill presumably is not intended to cut back on any opportunities for judicial review that may exist under current law. In order to avoid an unintended change in existing law, the phrase "in connection with a rule" should be inserted in the first sentence of subsection 627(d) after the phrase "any risk assessment required under this subchapter".

(2) Two changes should be made to subsection 627(e) -- one to clarify it internally; the other to clarify its relation to subsection 627(d) and to other provisions of law outside of S.746.

- What is now the last sentence of subsection 627(e) should be relocated directly after the first sentence because, if we understand it correctly, it relates to the first sentence, not to the second sentence, and it is somewhat confusing in its present location. In addition, the phrase

"or remain in effect" should be added after the words "take effect" because, in most cases, a rule will have taken effect long before a court issues its decision on judicial review.[22]

- What is now the second sentence of subsection 627(e) also needs clarification because it could be read to restrict the scope of judicial review under other statutes and might be viewed as undercutting the reference to the "arbitrary and capricious" standard of review in subsection 627(d) -- neither of which we assume was intended. In some cases, cost-benefit analyses and risk assessments may be subject to requirements of other laws in addition to S.746. Examples of such laws are the Toxic Substances Control Act, 15 U.S.C. § 2605, the Safe Drinking Water Act Amendments of 1996, 42 U.S.C. § 300g-1(b)(3), the Food Quality Protection Act of 1996, 21 U.S.C. § 346a(b), and the Accountable Pipeline Safety and Partnership Act, 49 U.S.C. § 60102(b). In the absence of S.746, a cost-benefit analysis or risk assessment performed in accordance with the requirements of these other laws would be reviewable under specific provisions of those laws or under the general judicial review provisions of the Administrative Procedure Act, 5 U.S.C. §§ 701-706. Pursuant to such review, an agency's inadequate compliance with a specific cost-benefit analysis or risk assessment requirement of one of those other statutes might be a basis for remanding or invalidating the rule. The fact that S.746 may establish essentially the same cost-benefit or risk assessment requirement should not change things -- *i.e.*, subsection 627(e) should not "trump" these other statutes by depriving a court of jurisdiction to remand or invalidate a rule where an agency has failed to comply adequately with a requirement imposed by the other statute. Nor should subsection 627(e) be read to imply that the results of an inadequate cost-benefit analysis or risk assessment cannot be considered by a court under subsection 627(d) in determining whether to remand or invalidate a rule as being arbitrary, capricious, an abuse of discretion, or unsupported by substantial evidence.

To avoid either of these implications, we suggest that what is now the second sentence of subsection 627(e) be revised to read as follows:

> "Except as provided in this subsection, the inadequacy of an agency's compliance with the specific requirements of this subchapter shall not in and of itself be the basis for remanding or invalidating a rule on the ground that the agency action was

[22] As a matter of "wordsmithing," we also would suggest that the phrase "giving due regard to prejudicial error" in the first sentence of subsection 627(e) be rephrased as "giving due regard to the principle of prejudicial error".

without observance of procedure required by law."

Savings Clause

Paralleling the clarifying change suggested above, we believe the judicial review "savings clause" in section 622(b) should be revised to read as follows:

> "Nothing in this subchapter shall be construed to alter or modify-
>
> (3) any opportunity for, or the scope and standard of, judicial review applicable under other statutes."

Substitution Risks

As pointed out by the Commission on Risk Assessment and Risk Management, the risk assessment component of a regulatory analysis --

> "must consider whether an option may cause any adverse consequences and determine what the tradeoffs among the different risks may be. One of the most important effects to consider is the potential for an option to increase one type of risk while reducing the risk of concern."[23]

As examples of this, the Commission points to cases where "[r]educing pollutant concentrations in one environmental medium may increase pollutants in another medium" or where "[b]anning one substance because it might cause one health risk may increase the use of another substance that is known to cause another health risk or whose health effects are not known."[24] Clearly, identifying and evaluating the potential "substitution risks" of a regulatory action should be viewed as a critical component of the risk assessment-regulatory analysis process for major rules.

S.746 recognizes this point to some extent. Thus, the term "substitution risk" is defined in section 621(11), and section 623(b)(2)(C) directs agencies to identify and evaluate substitution risks to health, safety, or the environment in the regulatory analysis for a major rule "when scientific information" on such risks "is reasonably available to the agency." These provisions certainly are helpful, but we believe three small modifications should be made in order

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[23] Risk Assessment Commission Report at 26.

[24] *Id.*

to ensure that substitution risks receive adequate attention in risk assessments and regulatory analyses for major rules.

First, the term "cost" in section 621(3) should be revised to make explicit that substitution risks are among the costs of a rule, which -- in any logical and practical sense -- they are. This could be done by inserting the phrase "and substitution risks" after the words "distributional effects"on page 4, line 18 of the bill.

Second, the text of what is now section 623(b)(2)(C) should be moved so that it is included as a subparagraph under section 623(b)(2)(A), which lists the components of a cost-benefit analysis for a major rule. That is where the provision logically belongs since a substitution risk is, after all, one of the costs (or "adverse effects") of a rule.

Third, section 624(d) should be revised to add a requirement that when scientific information is reasonably available, agencies should include in their risk assessments for major rules a description and evaluation of any substitution risks that are reasonably anticipated to result from adoption of the rule. This would simply conform the risk assessment provision of the bill to the regulatory analysis provision, since a substitution risk could not be identified and evaluated in the regulatory analysis for a rule unless it has been addressed in the risk assessment for the rule.

"Reasonable Alternatives" and "Flexible Regulatory Options"

In its Final Report, the Commission on Risk Assessment and Risk Management stated: "Risk managers and stakeholders should aggressively seek alternatives to command-and-control regulation to improve the efficiency and effectiveness of health and environmental protection and to reduce compliance and litigation costs."[25] We agree with this position and believe that S.746 should promote the analysis of cost-effective alternatives and "flexible regulatory options" (like market-based mechanisms and performance standards) more strongly than it does. To accomplish this, a definitional problem, discussed below, needs to be addressed.

The "reasonable alternatives" that agencies are directed to evaluate under S.746 are defined in section 621(8) so as to exclude regulatory options that the agency does not have authority to adopt under the statute granting it rulemaking authority. In such a case, neither the

[25] Risk Assessment Commission Report at 49.

agency, nor Congress, nor the public at large would know whether a regulatory option that is not authorized under the enabling statute might have achieved the rulemaking objective more cost-effectively and produced greater net benefits than the rule the agency adopted. By depriving Congress and the public of that information, we would miss an opportunity to consider whether the enabling statute should be amended so that the statutory objectives can be achieved more flexibly and cost-effectively in the future, or whether the rule itself should be disapproved by Congress pursuant to the Small Business Regulatory Enforcement Fairness Act review procedure.[26]

We are not suggesting that S.746 should allow an agency to adopt a regulatory option that is not authorized under the relevant enabling statute, even if that option would achieve the rulemaking objectives more cost-effectively and with greater flexibility for regulated entities than the other alternatives being considered. We do believe, however, that where such an option has been identified for a major rule, the agency should analyze the option and include the results of its evaluation in the regulatory analysis for the rule. This could be accomplished by deleting from the definition of "reasonable alternative" in section 621(8) the clause "and that the agency has authority to adopt under the statute granting rule making authority" which appears on page 6, lines 9-10 of the bill. Section 623(d) would remain unchanged. If the agency is not authorized to adopt the more cost-effective "reasonable alternative," it would simply say so in the explanation it provides under section 623(d)(2). Indeed, as noted in the previous footnote, that is precisely what section 623(d)(2)(A) seems to contemplate.

Peer Review

As noted above, independent peer review improves the scientific-technical basis for agency action while enhancing the credibility of the agency's final decision. Accordingly, we are pleased that section 625(a) requires peer review of risk assessments for major rules. We are concerned, however, that the threshold of $500,000,000 in annual costs (which has to be exceeded in order to trigger peer review of a cost-benefit analysis) is so high that cost-benefit analyses for major rules almost never will be peer reviewed. We urge the Committee to consider

[26] This problem is reflected in section 623(d)(2) under the bill. That provision appears to contemplate situations in which the underlying enabling statute precluded the agency from selecting a "reasonable alternative" whose benefits justify its costs or that is more cost-effective (or produces greater net benefits) than the rule actually promulgated. But, as defined in section 621(8), a "reasonable alternative" must be a regulatory option "that the agency has authority to adopt under the statute granting rule making authority." Thus, by definition, the agency will be unable to describe a "reasonable alternative" of the type that seems to be contemplated in section 623(d)(2).

reducing this threshold -- preferably to the same $100,000,000 annual cost figure that triggers peer review of risk assessments.

Conclusion

S. 746 is a responsible bill which will begin the process of ensuring that regulations are based on accurate risk and cost benefit assessments and are subjected to objective and scholarly peer review. It will help ensure what Vice President Gore described as "a government that works better and costs less" and that provides the American people "more benefits with fewer burdens."[27] That is why CMA strongly supports the goals of S.746.

[27] The Regulatory Plan, 63 Fed. Reg. 61203 (November 9, 1998).

Executive Summary

The Chemical Manufacturers Association is pleased to express strong support for the goals embodied in S. 746, The Regulatory Improvement Act, bipartisan legislation introduced by Senators Carl Levin (D-MI) and Fred Thompson (R-TN). The bill will go a long way toward improving the way federal agencies assess risks to public health and the environment and will help to ensure that solutions to these problems are cost-effective. CMA is particularly pleased with the bill's "transparency" provisions. Shining a light on agency processes and on the data and assumptions underlying regulatory decisions will enable all stakeholders – government, industry and the public -- to participate fully in the regulatory process, thereby improving the quality of agency decisions.

American consumers are not getting as much benefit as they deserve from their enormous expenditures on health, safety and environmental initiatives, nor are they fully able to hold agencies accountable for the quality, effectiveness, reasonableness and fairness of their decisions. S. 746 will assist in addressing these problems. The bill will:

- improve the quality of the scientific/economic information and related analyses upon which major agency rules are based;
- promote the public's "right to know" about the costs and benefits of regulations and the scientific and economic underpinnings of major agency rules;
- improve risk-based priority setting and comparative risk communication at Federal agencies; and
- enhance Presidential oversight and coordination of Federal regulatory actions.

By reforming the regulatory process in these respects, S.746 would improve the quality of those rulemaking decisions that have the most substantial consequences for the American society and economy. It also would enhance the credibility of regulators and boost public confidence in both the regulatory process and the regulations that emerge from that process. Importantly, the bill would achieve these objectives without disturbing the existing substantive criteria for agency rulemaking. Put simply, S.746 would help us create what Vice President Gore has described as "a government that works better and costs less" and that provides the American people "more benefits with fewer burdens."

CMA strongly supports the goals of S. 746. We believe, however, that the portion of the bill which unjustifiably excludes certain decisions under the Federal Food, Drug and Cosmetic Act from the scrutiny required by S. 746, must be deleted. CMA also has other technical/clarifying amendments which we hope will meet with the Committee's approval.

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Samuel L. Maury
President

Patricia Hanahan Engman
Executive Director

April 16, 1999

The Honorable Fred Thompson
Chairman, Committee on Governmental Affairs
United States Senate
Washington, D. C. 20510

Dear Mr. Chairman:

On behalf of The Business Roundtable, I am pleased to express our enthusiastic support for S. 746, the Regulatory Improvement Act of 1999. We are impressed with the strength of the bipartisan support for this important legislation. That support is built upon the foundation of cooperation and trust put in place by members of the 105th Congress and the Administration last year, and for that we congratulate you and Senator Levin.

The preponderance of expert testimony compiled during hearings on similar legislation in 1997 and 1998 clearly establishes that S. 746 will improve the federal regulatory process. Its provisions will enable regulators to identify and address priority issues sooner. Benefit/cost analysis, risk assessment and peer review are tools that regulators can use to implement important rules more swiftly because their decisions will rest upon a stronger base of scientific and economic analysis.

The job of corporate CEOs is not to gather the facts and data or to conduct the analysis personally, but to ensure that sound, analytical procedures have been followed and that valid and up-to-date scientific, economic, financial and other relevant data are used as part of systematic decision-making processes. These same considerations should apply to government agency heads, whose regulations can carry significant consequences and impose very large costs on the public.

That is why, in the final analysis, members of The Business Roundtable believe this bill will save more lives, speed the adoption of effective rules and provide greater benefits than the system that is in place today. We are prepared to work for its prompt enactment.

Sincerely,

John F. Smith, Jr.
Chairman & CEO
General Motors Corporation
Chairman, The Business Roundtable
Government Regulation Task Force

American Bakers Association
Serving the Baking Industry Since 1897

Anne G. Giesecke, Ph.D., Vice President Environmental Activities agiesecke@americanbakers.org

JUN 0 3 1999

May 28, 1999

The Honorable Fred D. Thompson
523 Dirksen Senate Office Building
United States Senate
Washington, D.C. 20510

Dear Senator Thompson:

On behalf of the American Bakers Association (ABA) thank you for your leadership on the regulatory improvement issue. More specifically, ABA would like to express deep appreciation for your vote on S. 746-The Regulatory Improvement Act of 1999.

The ABA strongly supports this and all legislation that attempts to bring sound science and common sense to agency decision making through regulatory improvement. Poorly written legislation and regulations that have resulted in high costs to industry with no measurable public benefit are well documented. While everyone must continue to fight the conditions of each bill and regulation, a broader approach to remedy the problem is also necessary.

Thank you again for your efforts, it is comforting to know that the baking industry is not fighting this battle alone. ABA will continue to actively participate in the development and passage of regulatory improvement bills. ABA looks forward to working with you in the future.

Sincerely,

Anne G. Giesecke, Ph.D

AIHC AMERICAN INDUSTRIAL HEALTH COUNCIL

April 20, 1999

The Honorable Fred Thompson
Chairman
Senate Governmental Affairs Committee
340 Dirksen Senate Office Building
Washington, DC 20510

Dear Senator Thompson:

On behalf of the American Industrial Health Council (AIHC), I am pleased to submit the enclosed statement for the hearing record on S. 746, the Regulatory Improvement Act of 1999.

AIHC is a broad based scientific organization representing manufacturers of consumer products, pharmaceuticals, petroleum, chemicals, motor vehicles, foods and beverages, high technology and aerospace products. Our mission is to promote the sound use of scientific principles and procedures in public policy for the assessment and regulation of risks associated with human health and ecological effects.

The Council's statement addresses several important issues: scientific peer review, risk assessment, use of default assumptions, and risk characterization principles. We welcome the opportunity to present these recommendations as a means for improving the federal rulemaking process.

If you have any questions or if we can provide you with any additional information, please contact me at (202) 833-2177 or by e-mail at gcamera@aihc.org.

Sincerely,

Gaylen Camera

Gaylen M. Camera, CAE
Executive Director

Attachment

STATEMENT OF THE
AMERICAN INDUSTRIAL HEALTH COUNCIL
SUBMITTED TO THE
SENATE GOVERNMENTAL AFFAIRS COMMITTEE
APRIL 21, 1999
HEARING ON S. 746, REGULATORY IMPROVEMENT ACT OF 1999

The American Industrial Health Council (AIHC) welcomes this opportunity to present its recommendations to improve the federal rulemaking process, specifically as they relate to scientific peer review, risk assessment, use of default assumptions, and risk characterization principles.

AIHC is a broad based scientific organization representing manufacturers of consumer products, pharmaceuticals, petroleum, chemicals, motor vehicles, foods and beverages, high technology and aerospace products.

AIHC's mission is to promote the sound use of scientific principles and procedures in public policy for the assessment and regulation of risks associated with human health and ecological effects. AIHC does not act as an advocate for any individual product or substance and does not advocate for or against any specific legislative proposal. Rather, AIHC's focus is, and always has been, on promoting and improving scientific risk assessment as a critical part of the risk management process.

Importance of Independent Scientific Peer Review

Peer review is the scientific community's principal method for assuring the quality of scientific data, the validity of risk assessment procedures, and the reliability of scientific conclusions and judgments. For more than twenty years, AIHC has dedicated substantial resources to advancing the role of peer review as a means to assure sound application of science in regulations. Consistent with AIHC's position, the 1983 NAS "Red Book" strongly emphasized peer review as an essential component of the risk assessment process.[1]

In 1995, AIHC undertook a study to evaluate the state of peer review practices within the Federal government. In response to the study's findings, AIHC developed and issued its Fundamental Scientific Peer Review Principles; a copy of these principles is attached to our statement. AIHC's Principles are intended to further scientific peer review across all government agencies and specifically recommend that:

- Each Federal agency head (or a designate) should be accountable for the implementation of quality peer review.
- Scientific expertise should be the highest priority in selecting individual peer reviewers.
- Peer review panels should be comprised of experts who are independent of, and external to, the agency that prepared the work product under review.

[1] National Academy of Sciences, *Risk Assessment in the Federal Government: Managing the Process*, Pages 156 - 160, Washington, DC: National Academy Press, 1983.

- Quality peer review should include a critical evaluation of all scientific aspects of risk assessment including consideration of the scientific conclusions, the adequacy of the scientific support for the proposed regulatory or policy decisions, and determination of whether the risk assessment supports a credible interpretation of the hazard and risks that are predicted.

AIHC respectfully commends to the Committee's attention the February 1997 report of the Presidential/Congressional Commission on Risk Assessment and Risk Management. The report emphasizes the crucial role of peer review in regulatory decision making. In fact, the Commission specifically recommends that peer review play a critical role in the evaluation of the quality of technical information used in regulatory decision making. In addition, the Commission endorses the concept that "expertise in the technical area under evaluation should be the primary criterion for members of peer review panels."[2]

Scientific peer review provides the best mechanism to assure the quality of scientific data used in regulatory decisions. Peer review should occur early in the regulatory process, and should be conducted in such a way as to provide a timely response to meet any agency's rulemaking requirements.

It is important to recognize that the scientific peer review process is not intended to serve as a mechanism for reviewing, modifying or repealing existing

[2] The Presidential/Congressional Commission on Risk Assessment and Risk Management, *Risk Assessment and Risk Management in Regulatory Decision-Making*, Volume 2, pages 103-106, February 1997.

rules. It is intended only as a process to assure the sound application of science in regulations as they are being formulated.

It is imperative not to confuse scientific peer review with other key elements of a federal agency rulemaking process, such as public participation and public comment. These mechanisms are distinct processes that are critical to developing reasonable, effective federal regulation.

Consequently, AIHC recommends that independent scientific peer review be incorporated as a key provision in any regulatory improvement legislation considered by the 106th Congress. For example, S. 746, the Regulatory Improvement Act of 1999, includes such a provision. AIHC's Fundamental Scientific Peer Review Principles and the recommendations of the Presidential/Congressional Commission on Risk Assessment and Risk Management can provide critical guidance.

Promoting Scientific Risk Assessment

AIHC believes that scientific risk assessment provides the optimal basis for making reasonable and sound regulatory judgments. Sound scientific risk assessments should consider all available data, as well as the relevance of those data to human risk. The Presidential/Congressional Commission concurs: "A good risk management decision is based on a careful analysis of the weight of scientific evidence ..."[3] "Because so many judgments must be made based on

[3] Presidential/Congressional Commission on Risk Assessment and Risk Management, *Risk Assessment and Risk Management in Regulatory Decision-Making*, Volume 1, Page 4, February 1997.

limited information, it is critical that *all* reliable information be considered."[4] AIHC also believes it is critical that the latest scientific data and understanding be incorporated into risk assessments. Further, the risk assessment process should be transparent so stakeholders, including the public, understand how the assessment was conducted, the assumptions upon which it is based, and the uncertainties inherent in the assessment.

Adoption of formal risk assessment guidelines would assure greater consistency and transparency in risk assessments throughout the federal government. The development of such guidelines would also assure that scientific risk assessments provide the most accurate and reliable basis for determining the risk reduction benefits of agency action. An accurate and reliable determination of expected benefits is essential to the subsequent determination of whether the expected regulatory costs are justified. The process for establishing such guidelines should include an opportunity for both public comment and external peer review. In addition, AIHC believes developing and implementing such guidelines will improve government rulemaking.

Use of Default Assumptions

It is vital that risk assessments consider all valid scientific data. Further, risk assessments should be based to the maximum extent feasible on actual data, especially site-specific or substance-specific data, instead of default

[4] Presidential/Congressional Commission on Risk Assessment and Risk Management, *Risk Assessment and Risk Management in Regulatory Decision-Making*, Volume 1, Page 38, February 1997.

assumptions. Many default assumptions currently in use are based on data that are more than 20 years old. It is clearly preferable to draw on both the general advances in biology and toxicology since that time, as well as the data available for a particular agent, than to rely on default assumptions. AIHC believes that only when relevant data are insufficient is it appropriate to consider default assumptions to supply the necessary data to complete a risk assessment. In any such circumstance, an agency should explicitly identify any default assumptions used.[5]

As outlined in AIHC's 1997 brochure "The Role of Toxicity Default Assumptions in Risk Assessment" (copy attached), AIHC believes that risk assessments should:

- Incorporate all available and applicable scientific data and models.
- Rely on expert consensus when data are limited but valuable inferences can be drawn.
- Employ defaults only when applicable data are either unavailable or of such questionable value that expert consensus dictates against their use.

By relying on actual data when available, federal regulators will simultaneously stimulate scientific research and make more sound risk-based decisions. By documenting the use of default assumptions, when relevant and applicable data are unavailable, greater transparency of both analysis and decision-making will result.

[5] National Research Council, *Science and Judgment in Risk Assessment*, pages 104-105, 1994.

Advancing Risk Characterization in Risk Assessment

Risk characterization is the final step in the risk assessment process and is intended as the integrative description of the results of hazard, dose-response and exposure evaluation. AIHC has evaluated this phase of the risk assessment process in great detail and in 1995 issued its Risk Characterization Guiding Principles. A complete copy of the principles is attached to this statement.

Risk assessors and risk managers alike use the risk characterization process as a bridge to link science and policy. Transparent, clear risk characterizations are the critical path to conveying scientific information and assumptions to risk managers, decision makers, and the public.

Conclusion

Scientific risk assessment is recognized in the United States as the foundation for the assessment and regulation of risks to human health and the environment. It is the scientific process of risk assessment that sets forth the nature and character of risks to human health and provides the foundation for evaluating the benefits (i.e., risk reduction) and other aspects of the risk management process.

AIHC strongly recommends that any regulatory improvement legislation include provisions for:

- a process of external, independent scientific peer review;

- the establishment of rigorous risk assessment principles to provide guidance for incorporating scientific information, modifying default assumptions, and communicating the complete risk characterization of the hazard and risk; and
- full and transparent characterizations of health and environmental risks.

AIHC appreciates the opportunity to submit this statement for the hearing record. We would be happy to address any questions raised by this statement.

FUNDAMENTAL SCIENTIFIC PEER REVIEW PRINCIPLES

June 1995

The head of each respective federal agency or a designate should be accountable for the implementation and quality of peer review.

The President or a designate should be responsible for implementing and ensuring consistency of peer review principles across federal agencies.

A quality peer review will contain the following elements:

- critical evaluation of all scientific aspects of the risk assessment, including methodologies, exposure factors and scenarios, and the risk characterization;
- interpretation of scientific conclusions in the context of accepted biological principles;
- adequacy of scientific support for the proposed regulatory or policy decision; and
- a determination concerning whether the risk assessment supports not only a credible interpretation of what is known, but also a credible interpretation of the hazard and risk that is predicted.

A flexible process should be developed that allows for a level of peer review commensurate with the importance of the issue.

The highest priority in selecting individual peer reviewers should be given to scientific expertise.

No expert candidate for a peer review panel should be excluded from consideration on the basis of affiliation.

Peer review panels should be composed of experts independent of and external to the agency that prepared the work product to be reviewed.

The panel should include a balance of experts.

The response to peer review comments by the federal agency should be in writing, and should address all views and opinions of the peer review panel.

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American Industrial Health Council

Advances in Risk Characterization

November 1995

ADVANCES IN RISK CHARACTERIZATION

Introduction

Concerns about the possible risks associated with industrial activities lead decision makers to seek ways to understand and quantify risks, as well as to evaluate strategies which may reduce human and ecological risks. Risk assessments have been used by decision makers to support a range of risk management decisions regarding industrial activities, including:

- establishing regulatory standards for a chemical or process technology
- setting ambient and/or occupational exposure standards
- selecting raw materials, products, or process technologies
- establishing cleanup standards for contaminated areas

The most useful risk assessments are those based on site-, source-, and/or situation-specific data. However, risk assessments often rely on limited information. Some degree of variability and uncertainty is inherent in all risk assessments, making complete characterization of risk and subsequent risk management decisions more challenging. *Risk assessors and risk managers alike use the risk characterization process as a bridge to link science and policy.*

The American Industrial Health Council (AIHC) continues to work toward improving the risk characterization process. In 1991, AIHC co-sponsored a workshop to increase awareness of the importance of risk characterization as a link in the overall risk assessment and risk management process, and to develop suggestions and recommendations for its improvement. AIHC published a summary of the workshop in 1992 entitled *Improving Risk Characterization*[1]. Since then, further advancements have been made in risk characterization. This summary addresses the significance of and recent improvements in the risk characterization process.

Defining Risk Characterization

In 1983, the National Research Council (NRC) described risk assessment as a four-step process: hazard identification, dose-response evaluation, exposure assessment, and risk characterization. The NRC defined risk characterization as "the process of estimating the incidence of a health effect under various conditions of human exposure" [2]. AIHC's *Improving Risk Characterization* refined this definition of risk characterization as "the interactive process of extracting and integrating decision-relevant information from hazard, dose-response, and exposure evaluations and rendering it comprehensible to a diversity of users" [1]. The 1992 workshop also prompted AIHC to develop guiding principles for risk characterization [3]. In 1995, the U.S. Environmental Protection Agency (EPA) issued a policy statement and guidance for risk characterization which used a similar definition and adopted a similar set of guiding principles. The policy stated that "risk characterization integrates information from the preceding components of the risk assessment and synthesizes an overall conclusion about risk that is complete, informative, and useful for decision makers" [4].

Risk characterization is the interactive process of extracting and integrating decision-relevant information from hazard, dose-response, and exposure evaluations and rendering it comprehensible to a diversity of users.

American Industrial Health Council [1]

Risk characterization integrates information from the preceding components of the risk assessment and synthesizes an overall conclusion about risk that is complete, informative, and useful for decision makers.

U.S. Environmental Protection Agency [4]

Risk Characterization Principles

General principles for performing risk characterization have been identified by AIHC [3] and EPA [4]. General guidance for implementing these principles has also been developed [4,5]. The following sections provide brief discussions of the fundamental principles, their implications, and implementation. *AIHC believes that following these principles will result in improved risk characterization and more informed risk management decisions.*

Iterative Process

In its 1994 review of the use of science and judgment in risk assessments for hazardous air pollutants, the NRC advocated an iterative approach to risk assessment starting with a screening analysis and progressing to more comprehensive assessments as warranted [6]. Using an iterative process, risk assessors can determine the adequacy of the information at any stage and decide whether another iteration of

AIHC Risk Characterization Guiding Principles

- Risk characterization is an iterative process designed to be interactive with end-users.
- Any quantitative description of risk, exposure, potency, or other risk elements should be expressed as a range.
- Risk characterization should include a summary of the key issues and conclusions of each component of the risk assessment.
- Risk characterizations should include a discussion of ongoing, planned, or potentially useful research.
- Risk characterization should be consistent but recognize the unique characteristics of each specific situation.
- Risk characterization should include, at least in a qualitative sense, a discussion of how a specific risk and its context compares with other health risks.
- Risk characterization should always accompany any presentations of risk management decisions and/or recommended actions.
- Risk characterization should function as a means by which societal considerations can be integrated with technical risk information.

the analysis is required. The NRC suggested that iterations should be made until "(1) the risk is below the applicable decision-making level, (2) further improvements in the scientific knowledge would not significantly change the risk estimate, or (3) ... the stakes are not high enough to warrant further analysis" [6]. The basic concept underlying the iterative approach is that uncertainty in the risk assessment decreases as the comprehensiveness of the risk assessment increases. This may seem counterintuitive since the quantitative results presented for a screening analysis might be point estimates of risk, while those for a more comprehensive analysis might be distributions of risk. However, these different presentations simply change the *representation* of uncertainty, not the actual uncertainty in the risk. *Uncertainties about risks can be reduced only by obtaining better information.*

Distinguishing Variability and Uncertainty

Variability: knowledge of heterogeneity in a well-characterized population, usually not reducible through further measurement or study

Uncertainty: ignorance about a poorly-characterized phenomenon or model, sometimes reducible through further measurement or study

Reference 7

Categories of Uncertainty

Model uncertainty: error from the use of simple scientific models to represent reality

Measurement uncertainty: error associated with scientific measurements

Data gap uncertainty: error associated with the reliance on estimates or assumptions in the absence of the desired information

References 8,9

Using an iterative approach, risk assessors can identify key uncertainties. In turn, the iterative approach encourages the pursuit of targeted research, providing a much needed incentive for building a base of strong scientific information. This incentive can be sustained, however, only if the information is used by risk managers to make better and more efficient decisions. Challenges associated with implementing

an iterative approach include clearly defining the interaction between the risk assessor and risk manager and developing criteria for judging the adequacy of an analysis.

Full Characterization of Quantitative Risk Estimates

Quantitative risk assessments which present only point estimates of risk do not fully convey the range of information available, and do not adequately deal with variability and uncertainty [6]. To fully characterize risks, information on the range of exposures for multiple risk descriptors (e.g., central tendency or high end of individual risk, population risk, risk within or to identifiable subpopulations) should be presented with an emphasis on distinguishing between variability and uncertainty [4]. The NRC succinctly explained the fundamental differences between variability and uncertainty as follows [6]:

> Uncertainty forces decision makers to judge how *probable* it is that risks will be overestimated or underestimated for every member of the exposed population, whereas variability forces them to cope with the *certainty* that different individuals will be subjected to risks both above and below any reference point one chooses.

Comprehensive risk characterizations should include multiple sets of results for different types of models and/or different risk descriptors, ranges and confidence intervals, as well as (or, preferably, instead of) point estimates of risk. Implementing this principle requires that variability and uncertainty be identified in risk models from start to finish.

Only through a full characterization of risks can point estimates be placed into an appropriate quantitative context.

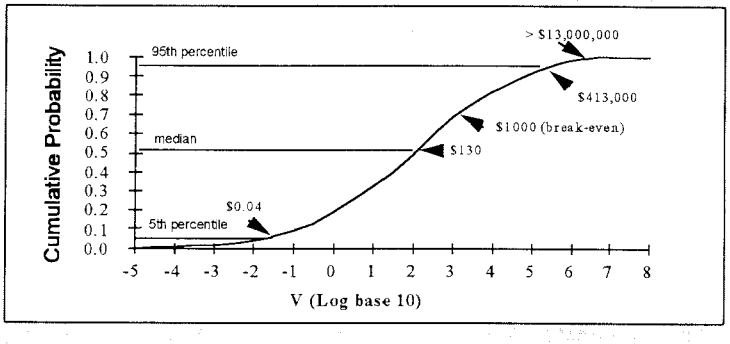
Only through a full characterization of risks can point estimates be placed into an appropriate quantitative context. For cancer risk assessments, the NRC suggests placing point estimates in context by thinking of risk in the following way: "We are Y% certain that the risk is no more than X to Z% of the population," where X, Y, and Z are, respectively, the point estimate of risk, the level of confidence that the risk is no higher than the point estimate, and the percent of the population to which the point

Characterizing Quantitative Risk Estimates

Decision problem
Suppose you (a risk manager) have to decide whether to invest $1,000 and receive an uncertain return on the investment (V). Different risk assessors provide you with their *risk characterizations* for V.

Information

- *Risk Assessor A* tells you a "plausible upper bound" for V is $413,000, which corresponds to the upper 95th percentile. It is unlikely V will exceed the estimate of $413,000, and it is very likely to be lower.
- *Risk Assessor B* suggests that a "best estimate" is more relevant for decision-making purposes, and informs you that if you invest, you have a 50-50 chance of getting a V value above $130.
- *Risk Assessor C* informs you the investment could lead to a very large pay-off, and tells you that the expected value of V is over $13,000,000.
- *Risk Assessor D* feels unable to predict V with any reliability. He offers "reasonable certainty" that V will be between $0.04 and $413,000, but is unwilling to offer advice about which, if either, end of the range is more likely.
- *Risk Assessor E* shows you the distribution of V which places all of the previous information into context, and asserts that if you can understand the uncertainty, you are better prepared to deal with it.



Realization
Any single point estimate (risk assessors A, B, and C) or qualitative information (risk assessor D) alone is insufficient and misleading. Risk managers must ask the questions: How does this point estimate fall into the full spectrum of risk? Should I ask for more information?

(Adapted from reference 10)

estimate applies for a variable population [5]. The results of non-cancer risk assessments are typically estimates of the *likelihood* of risk using a hazard index, and not an actual measure of risk [6]; consequently, careful consideration should be given to an explanation of what is being quantitatively characterized.

Techniques also exist for exploring the significance of key inputs and uncertainties, as well as the value of improved information (e.g., sensitivity analyses, decision analyses, and/or information analyses). Research continues to provide new insight about developing distributions, analytically dealing with variability and uncertainty in risk models, and incorporating expert judgment.

Qualitative Discussion

Every risk assessment contains variability and uncertainty. To support quantitative estimates of risk, it is critical to provide qualitative information to explain and justify assumptions and methodologies. Risk characterizations should explain key assumptions (including default assumptions mandated by policy), uncertainties, and conclusions in the other parts of the risk assessment. Risk characterization should also discuss confidence in the methodologies used, the impact of alternative choices, and the limitations of the analysis. Since independent risk assessors can generate vastly different estimates for the same risk by using different assumptions, risk estimates must be accompanied by a list of assumptions on which they rely.

If applicable, the risk characterization should include a discussion about ongoing or planned research that may influence the outcome of a given risk assessment. Adequate justification and a detailed plan for how additional data would be used must be presented before more research is initiated.

Transparency and Clarity

Risk assessments require transparency and clarity. In particular, *the risk characterization should distinguish between assumptions based on science and assumptions based on policy judgments.* The risk characterization should be explicit about the basis for choices and how these choices affect the results. In order for risk characterizations to be transparent and clear, they should specify and describe all scientific and policy assumptions (including the use of default values and methods). As part of the risk characterization, risk assessors should

examine all relevant information and address issues of conflicting data and judgments. Transparency and clarity in the risk characterization will help the risk manager determine whether there is adequate information, as well as help the risk manager choose between alternative risk management options.

Simple, Consistent Terminology

Risk characterization language should be consistent and simple to minimize miscommunication between risk assessors, risk managers, and end-users. Broad use of consistent terminology should accommodate the unique characteristics of specific risk assessment scenarios. Use of standard terminology will also facilitate comparisons of different risks, meaningful evaluation of risk-risk trade-offs, and the distinction between risk communication and risk characterization.

Comparisons to Other Risks

Risk characterization should place risks into context and include a qualitative discussion of how a specific risk compares with other health or ecological risks. Familiar points of reference should be included to provide context for the risk manager and the public as they review the results of the risk assessment.

Comparing risks is difficult. It is an approach that should be used cautiously. Risk assessors and risk managers can identify the strengths and limitations of comparing risks by considering the following questions:

- How should variability and uncertainty be dealt with in risk comparisons, and which risk descriptors should be compared?
- What are the limitations of comparisons being made?
- Are the scope and degree of analysis for different risk assessments comparable?

Risk Characterization: A Bridge to Informed Decision Making

Risk characterization should serve as the vehicle by which risk assessors convey scientific information and assumptions to risk

managers. In turn, risk characterizations should always accompany any presentations of risk management decisions and recommended actions. The risk characterization process can:

- improve risk management decision making and provide insight relevant to potential decisions
- give an integrated view of the scientific evidence
- identify key assumptions, the reason for their use, and the extent of scientific consensus about those assumptions
- identify the effect of reasonable alternative assumptions on conclusions and estimates
- outline specific ongoing or planned research projects that may reduce uncertainty in the risk estimate
- provide a statement of confidence in the risk assessment and its components
- facilitate effective risk communication
- function as a means by which societal considerations can be integrated with technical risk information

What's Next?

As of this writing, a number of important, ongoing activities could influence the scope, process, and application of risk characterization in the future. These activities include the following:

- **Report from the NRC Committee on Risk Characterization**
  The NRC Committee, formed in 1994, was charged with evaluating current risk characterization efforts and recommending improvements. The NRC Committee is expected to release its report in 1996.

- **Risk Legislation in the 104th Congress**
  While EPA is committed to improving risk characterization via its internal policy and guidance [4], no statutory requirement exists for implementing the policy. In the 104th Congress, a number of regulatory reform bills have been introduced which would require risk characterization as part of all risk assessments. To date, the outcome of this proposed legislation is unclear.

- **Implementation of EPA Risk Characterization Guidance**
  Completion of EPA case studies aimed at developing outlines of questions to be addressed in risk characterizations, as well as iteration of EPA guidance and devotion of resources to address key outstanding issues, will contribute significantly to advances in risk characterization in the future.

AIHC continues to support and participate in initiatives that advance risk characterization, and invites collaboration with other organizations interested in improving risk assessment, risk characterization, and risk management decision making. The Council believes that improving the risk characterization process will be a mechanism for identifying, exploring, and resolving scientific uncertainties and disagreements. Improvements will also empower the risk manager to make better decisions with more complete information, identify areas for additional research, and strengthen the use of risk assessment as a risk management tool.

Acknowledgement

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THE ROLE OF TOXICITY DEFAULT ASSUMPTIONS IN RISK ASSESSMENT

American Industrial Health Council
August 1997

THE ROLE OF TOXICITY DEFAULT ASSUMPTIONS IN RISK ASSESSMENT

This brochure provides a brief overview of the role of toxicity default assumptions in risk assessment, summarizes the major toxicity default assumptions used by regulatory agencies for human health risk assessment, discusses how data are or may be used in place of defaults, and outlines AIHC's position on the use of toxicity defaults in risk assessment.

Contents

What Is a Toxicity Default Assumption?

When specific data on the toxicity of a substance in humans are not available, default assumptions are typically used to predict potential human health effects by modifing existing animal toxicity data. Assumptions are made about the mechanism of action of the substance, its rate and mode of metabolism and excretion, and its distribution and impact on various organs and tissues. These assumptions are termed "toxicity defaults" and are commonly used in risk assessments conducted by or for regulatory agencies in the United States.

Toxicity defaults are used when data about a specific toxicological event are unavailable or uncertain (e.g., whether humans respond like animals). Established by government regulatory agencies, defaults combine general scientific concepts about the event in question with policy judgments on the accepted degree of conservatism for dealing with uncertainties in toxicity data. As a result, toxicity defaults typically integrate both science and policy. Not surprisingly, the "policy" portion of the default reflects the experience, judgment, and objectives of the federal or state regulatory authority making the determination. Thus, different regulatory agencies may use different toxicity defaults. For example, the toxicity defaults used to develop safe levels of exposure for workers (healthy adults) and the general population (including the young, elderly, and infirm) may differ.

Toxicity defaults typically integrate both science and policy.

Toxicity defaults are not intended to be applied universally in all risk assessments, nor are they intended to be binding or rigid. They are generic assumptions that "fill in the gap" when essential information is missing.

Background

Federal agencies began to systematically conduct risk assessments in the 1970s. In 1976, the US Environmental Protection Agency (EPA) issued interim guidelines for conducting risk assessments on suspected carcinogens (EPA 1976). EPA subsequently published updates to its original guidelines in 1986 (EPA 1986) and proposed additional revisions in 1996 (EPA 1996). In each version, the Agency provided general guidance on the recommended use and application of toxicity defaults.

Prior to the release of EPA's first and second updates to its carcinogen risk assessment guidelines, the National Research Council (NRC) evaluated the risk assessment process in the federal government (NRC 1983). In 1994, the NRC released a comprehensive report that further described the evolving process of risk assessment (NRC 1994). In both NRC reports, toxicity defaults are considered necessary elements of a risk assessment when scientific data of adequate quality are missing.

Defaults generated in the mid-1970s were based on the most current scientific information available. Since that time, significant scientific advances have occurred which justify revisiting the scientific data underlying the use of certain default assumptions. Despite these advances, outdated toxicity defaults are still routinely applied in risk assessments.

The Scientific Basis for Common Toxicity Defaults

Several toxicity defaults commonly appear in human health risk assessments. This section provides a brief perspective on the science underlying eight of these toxicity default assumptions. Most of the following assumptions appear as standard defaults in EPA risk assessments. Unfortunately, the scientific basis for many of these has never been clearly defined by the Agency. The NRC (1994) called attention to this omission and encouraged EPA to disclose the scientific basis for the default assumptions it uses in human health risk assessments.

Toxicity defaults are not intended to be binding or rigid.

- Test animals are appropriate models for humans. This assumption forms the basis for conducting toxicity studies in animals (Klaassen and Eaton 1993). While the principle that test animals are appropriate models for humans is generally valid, there are significant exceptions. Studies show that some animal tumor responses do not occur in humans.

- High-dose exposures in animals accurately predict potential adverse effects at lower doses in humans. Although widely accepted in years past, particularly in cancer testing and research, recent research challenges this assumption. Differences in metabolism, physiology, and many other factors change the way animals and humans react at different doses.

- The most sensitive sex, strain, species, and site of action are proper bases for risk assessment. When relevant data in humans are lacking, animal data from the most sensitive species, sex, strain, and site are substituted. This default assumption is adopted as policy because it assumes that humans are as sensitive as the most sensitive species tested (EPA 1986). However, available data indicate that certain species are not always appropriate models of the human response because of differences in body chemistry and physiology.

- The most sensitive response is used as the basis for risk assessments. The effects observed in experimental animal studies are assumed to be relevant to, and predictive of, effects occurring in humans. Thus, in order to be protective of human health, data on the most sensitive endpoint are selected for use in risk assessments. The validity of this default, however, is increasingly being questioned as technology allows the detection of more subtle responses. As research continues to elucidate these new responses, the term "toxicity" may lose its historical meaning. Subtle responses may be viewed not as toxic effects, but as biological perturbations that may or may not be predictive of toxic effects.

- Doses from animal toxicity tests can be scaled to equivalent human doses based on body weight. Because most toxicology studies are conducted in small laboratory animals, a procedure for converting animal doses to equivalent human doses is necessary. This procedure is called allometric scaling. Recently, EPA and FDA adopted a consistent approach which adjusts doses based on metabolism, a factor assumed to be related to body weight. Still, this scaling method generally assumes that humans are more sensitive than test animals.

- Risks for long-term exposure can be determined from short-term studies by assuming that toxic effects are a constant product of dose and exposure duration (CxT). This default assumes that responses to chemical exposures are related mathematically to the amount and duration of exposure. For example, one year of exposure to a dose of a chemical is assumed to produce the same effect as half the dose given for two years. However, thresholds exist below which no adverse responses occur. Low concentrations of some chemicals can be removed by the body without incident. This CxT assumption is frequently applied in studies of human populations (i.e., epidemiology), leading to inaccurate and overly conservative estimates of acceptable exposure levels. Consequently, CxT adjustments may conservatively, and often erroneously, estimate acceptable or safe dose levels that are dramatically below the threshold dose.

- Factors of up to 10 account for individual sources of uncertainty. Acceptable daily human exposure limits for toxic effects other than cancer are customarily derived by dividing the dose level in animals at which no adverse effects occur by factors of 10. The basis for these factors varies. When combined, these uncertainty factors may range from 10 to as much as 10,000 or more. In cases where very little or no data are available, regulatory agencies may rely upon two or more of the following factors: a factor of 10 to account for sensitive human populations, a factor of 10 to account for extrapolation from animals to humans, and a factor of 10 to account for toxicity from long-term exposures when only short-term studies in animals are available. Such factors account for uncertainties associated with applying each of the

already conservative assumptions discussed. Recently available data suggest, however, that factors less than 10 are in many cases more appropriate (Naumann and Weideman 1995). In addition, improved statistical procedures exist to account for uncertainty (e.g., probability techniques for combining uncertainties), thus allowing some defaults to be replaced (Dourson et al. 1996).

- At low doses, dose-response curves are linear for carcinogenicity. EPA has used a mathematical procedure called the linearized multistage model as the default carcinogenicity model for many years. The model estimates responses at exposures that are too low to be tested in the laboratory. The primary default assumption in the model is the theory that a single molecule of a chemical can alter DNA and induce cancer. That is, there is no threshold for the effect. At the time EPA adopted this default option, little was known about the mechanisms of carcinogenesis. In recent years, however, scientists have extensively studied the cancer process and have found that threshold levels below which cancer does not occur do sometimes exist. In addition, researchers have identified other mechanisms that do not involve direct interaction with DNA (Clayson and Iverson 1996). Using new information, risk assessors can replace the low-dose linear model with biologically based or case-specific models (Frederick 1993; Sielken et al. 1995).

Available scientific data should be incorporated into risk assessments before applying toxicity default assumptions.

Toxicity Defaults Versus Real Data

Toxicity defaults were originally intended to bring consistency, technical quality, and necessary conservatism to the risk assessment process in the absence of data. In the 1970s, defaults reflected currently available scientific concepts. However, scientific knowledge about toxicology and risk assessment has increased tremendously over the past twenty years. Given this increased understanding, scientists now question the validity of many toxicity defaults and, more importantly, their use when data are available. Although government agencies have encouraged the use of data in place of toxicity defaults in policy statements, in practice, these data are infrequently used. Defaults continue to be routinely applied.

Toxicity defaults should serve as "interim guides" providing bridges for gaps in scientific understanding until adequate data are collected.

In recent years, EPA reevaluated specific cases where toxicity defaults were not applicable in human risk assessments. The following example demonstrates how one such reevaluation resulted in a departure from a specific default leading to more accurate risk assessments.

In 1991, a Technical Panel of EPA's Risk Assessment Forum released a report discussing the relevance of specific kidney tumors observed in male rats to humans (EPA 1991). Experimental studies demonstrated that some chemicals induce kidney tumors in male rats via a mechanism involving the accumulation of the protein alpha$_{2u}$-globulin in the male rat kidney. This accumulation initiates a series of events that ultimately leads to the development of kidney tumors. However, the development of these tumors is both sex- and species-specific. Female rats and other experimental animals exposed to the same chemicals at the same doses do not develop these particular tumors. Because humans do not respond like male rats in the development of kidney tumors via this mechanism,

EPA concluded that (1) such tumors are not relevant to human health risk assessments, and (2) they should be distinguished from kidney tumors induced by other mechanisms. In 1997, the Presidential/Congressional Commission on Risk Assessment and Risk Management reiterated the conclusions of the Technical Panel.

Conclusions

Toxicity defaults will and should continue to be an integral part of the risk assessment process. Although scientific research continues to shed light on uncertainties and data gaps, it will be some time before observations from animal toxicology studies can be objectively evaluated and completely understood in terms of their human relevance without reliance on defaults. Nevertheless, to provide the most realistic and relevant risk assessments, efforts to better incorporate scientific information are crucial.

Toxicity defaults should serve as "interim guides" providing bridges for gaps in scientific understanding until adequate data are collected. Toxicity defaults currently used in risk assessments are based on scientific concepts that are over twenty years old. Yet, information is available in many cases that justifies replacing toxicity defaults with sound scientific data. Full use of available scientific information will advance the development of risk assessments that accurately reflect the current state of the science and yield more accurate and realistic risk values.

Public health protection is best served by encouraging the development and application of new scientific data for regulatory purposes. AIHC urges risk assessors and risk managers to examine and incorporate available scientific data into risk assessments before applying toxicity default assumptions.

AIHC's Position on the Use of Toxicity Default Assumptions

The American Industrial Health Council (AIHC) recognizes the need for toxicity defaults in risk assessment and fully supports their use under appropriate circumstances. However, the Council is concerned that toxicity defaults are being used differently than originally intended. Rather than using toxicity defaults for screening purposes or to provide conservative estimates of risk in the absence of data, defaults are often applied without regard for existing data that may support a different approach or a change in magnitude of a default.

Toxicity defaults remain a necessary component of the risk assessment process. After careful study, AIHC concludes that toxicity default assumptions are an important risk assessment tool but should not be routinely applied when scientific data of adequate quality are available.

The following principles were developed by AIHC to guide risk assessors in re-thinking the current procedure for employing default assumptions in risk assessment. AIHC believes that these principles will result in more scientifically valid risk assessments. In a step-wise fashion, risk assessors should:

- Incorporate all available and applicable scientific data and models.
- Rely on expert consensus when data are limited but valuable inferences can be drawn.
- Employ defaults only when applicable data are either unavailable or of such questionable value that expert consensus dictates against their use.

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April 21, 1999

The Honorable Fred Thompson
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The Honorable Carl Levin
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Washington, D.C. 20510

Dear Senators:

We are writing on behalf of the nation's governors, state legislators, and local elected officials to support the Regulatory Improvement Act (S. 746). The proposed bipartisan legislation would greatly assist state and local governments in assessing the costs and benefits of major regulations. This bill would lead to improved quality of federal regulatory programs and rules, increase federal government accountability, and encourage open communication among federal agencies, state and local governments, the public, and Congress regarding federal regulatory priorities.

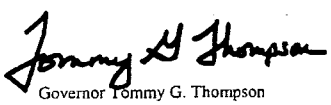
The Regulatory Improvement Act could also clarify the intent of the 1995 Unfunded Mandates Reform Act (UMRA) by requiring agencies to develop an effective process for local input into the development of regulatory proposals and prevent regulatory proposals that contain significant unfunded federal mandates. This legislation builds on executive order 12866 by codifying many of its provisions. The analyses and assessments included in your legislation are essential for ensuring that government resources are utilized to produce maximum benefits for consumers and those who are regulated.

Enactment of the Regulatory Improvement Act and the Regulatory Right to Know Act are part of a larger federalism agenda that the state and local government associations are working towards this year. We applaud your efforts to encourage greater accountability with regard to the burden of costly federal regulations on state and local governments. The changes proposed would, we believe, benefit all of our taxpayers and constituents. We look forward to working with you in securing enactment of this legislation.

Sincerely,

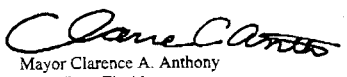
Governor Thomas R. Carper
State of Delaware
Chairman, National Governors' Association

Representative Dan Blue
North Carolina State House of Representatives
President, National Conference of State Legislatures

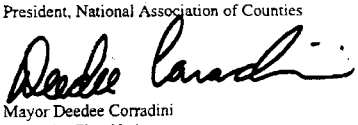


Governor Tommy G. Thompson
State of Wisconsin
President, Council of State Governments

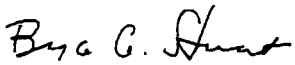
Commissioner Betty Lou Ward
Wake County, North Carolina
President, National Association of Counties



Mayor Clarence A. Anthony
South Bay, Florida
President, National League of Cities



Mayor Deedee Corradini
Salt Lake City, Utah
President, The U.S. Conference of Mayors



Bryce Stuart, City Manager
City of Winston-Salem
President, International City/County
Management Association

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April 16, 1999

The Honorable Fred Thompson
Chairman, Committee on Governmental Affairs
United States Senate
Washington, DC 20510 – 6250

Dear Mr. Chairman:

The Environmental Council of the States (ECOS) joins you in supporting requirements for cost benefit analysis and risk assessment in the development and promulgation of major rules. ECOS is the national non-partisan, non-profit association of state and territorial environmental commissioners.

We support the consideration of cost benefit analysis, because to do otherwise is to risk mis-application of limited resources. We support risk analysis because to do otherwise is to attack the wrong problems. Expanding the participation of state and local government officials in the development of national environmental requirements can only strengthen the final products.

The unanimity of support you have obtained from the National Governors' Association, the National League of Cities, the Council of State Governments, the National Conference of State Legislatures, the U. S. Conference of Mayors and the National Association of Counties demonstrates how important this issue is to elected officials. I hasten to assure you that it is equally important to those appointed officials who carry out the day-to-day management of the states environmental programs.

Sincerely,

Robert W. Varney
Commissioner
New Hampshire Department of Environmental Services
President, Environmental Council of the States

HR 7470

Buyers Up • Congress Watch • Critical Mass • Global Trade Watch • Health Research Group • Litigation Group
Joan Claybrook, President

April 29, 1999

Honorable Fred Thompson, Chairman
Honorable Joseph Lieberman, Ranking Member
Senate Governmental Affairs Committee
Washington, D.C. 20510

Dear Senators Thompson and Lieberman:

Attached is a response to John D. Graham's April 21, 1999, testimony before your committee on S. 746, the "Regulatory Improvement Act of 1999." I would like to request that it be included in the record.

Sincerely,

Joan B. Claybrook
President

attachment

Response to John D. Graham Testimony on Auto Safety and Fuel Economy

In his April 21, 1999 testimony before the Senate Governmental Affairs Committee on S. 746, John D. Graham provided an inaccurate and incomplete account of the National Highway and Traffic Safety Administration's rulemaking on passenger airbags and on fuel economy standards.

This account was the basis for Mr. Graham's conclusion that "each of these regulatory decisions and subsequent actions by Congress might have been quite different if the agency had performed the kinds of analyses envisioned in S. 746." *Testimony of John D. Graham, p. 7.*

To correct the record on NHTSA's passenger airbag rulemaking:

1. **Automakers greed, not NHTSA standards, are responsible for installation of airbags that endangered children**

NHTSA's occupant protection standard 208 which took effect in 1988 permitted manufacturers to install airbags **or other passive restraints** to meet the compliance requirements. It established injury **performance standards** that must be met, not **design** standards that specify the types of systems, such as airbags or passive safety belts. Performance standards set a benchmark and leave it up to the regulated companies to decide how to meet it. Thus, until 1997 when the Congress (not the NHTSA) mandated installation of air bags, manufacturers could use any type of compliant automatic restraint system.

The NHTSA standard requires that these restraints work effectively **in crashes up to 30 mph** into a solid barrier using an instrumented surrogate representing an average size male to measure injury levels. If a manufacturer chose to install air bags, the standard did not require air bags that deploy with a particular level of force, at a particular crash force threshold, or in a particular way. Manufacturers were given great discretion. A number of manufacturers chose to install air bags because they were most popular with the public, but at least some of them never tested their air bags to measure the effectiveness with children or smaller adult dummies or other surrogates as due care responsibilities obviously require. Nor did some conduct any tests at low speeds impacts below 30 mph in which cheaper sensors can fail to immediately recognize the severity of the crash and inflate the air bag late. Late deployment can result in air bags coming in contact with occupants while they are inflating, causing harm. And manufacturers did not immediately warn their customers about the dangers they knew to exist with the designs they selected to sell. Almost all of the people who have been killed due to airbags have been children or small women who **died in low speed crashes below 20 mph, a type of crash clearly covered by the standard.**

2. **Automakers knew about the danger to out-of-position children 25 years ago and knew which air bag designs and technology to use to protect children - they just didn't use it**

General Motors' first air bag design from 1974-76 had dual inflation capabilities precisely to protect children. And they were successful. But until this year, manufacturers refused to use this life saving element in their air bags. Furthermore, after the 1977 standard was issued NHTSA took steps to ensure that manufacturers were fully informed about the best available technology before the standard took effect. The agency contracted with several independent airbag experts to review the standard and to recommend design features that would protect children. Papers detailing the results and experts' recommendations were presented at international conferences attended by all the manufacturers world wide, and sent to all major manufacturers. General Motors, which had raised concerns about child safety in a notice to NHTSA in October of 1979, withdrew that complaint in December 1979 due to widely available information about technology and design options that resolved the problem. When the occupant restraint standard was reissued by Secretary of Transportation Elizabeth Dole in 1984 (following the 1983 Supreme Court decision), the Department specifically referenced concerns about out-of-position children and the NHTSA's extensive 1980 outside review and recommendations in the final rulemaking document (which every manufacturer reads).

Unfortunately, only Honda, among all the manufacturers, adopted any of the primary recommendations from the 1980 NHTSA review for the systems they started offering for sale under the 1984 rule in the late 1980's and early 1990's. Honda installed a top-mounted vertically deploying air bag that climbs up the windshield as it inflates, keeping it away from the occupants. No manufacturer used the dual inflation system. However, after the adverse publicity about the air bag deaths, a number of manufacturers started changing their designs. Many now install top mounted vertically deploying systems, and the sensors are electronic and more adaptable. Others are beginning to offer dual inflation systems. Most companies, now chastened from the bruising public drubbing they have taken for their lousy air bag designs, have been working as well on suppression systems, deep dish steering wheels and much more. And the Congress in 1998 decided that the discretion afforded manufacturers by NHTSA had been abused and required the agency to issue a much more demanding standard to specifically test with small adult and child dummies, which is now in progress.

Thus contrary to Mr. Graham's account, outside independent experts did review the science behind the standard, and did make recommendations on design and technology to maximize passenger safety. Their recommendations included dual inflation and top mounted vertically inflating airbags, as well as other technological safety features ignored by the manufacturers.

Nothing in S. 746 would have made airbags safer for children:

a. S. 746 asks agencies to give preference to "flexible regulatory options" - defined as "regulatory options that permit flexibility to regulated persons in achieving the objective

of the statute as addressed by the rulemaking, including regulatory options that use market-based mechanisms, *outcome oriented performance-based standards,* or other options that promote flexibility. [Section 621(6) emphasis added]. This is exactly what NHTSA issued.

b. S. 746 forces agencies to give more consideration to industry compliance costs. The cost-benefit analyses and net benefits determination required by Section 623 would have made it harder for NHTSA to issue a more protective standard.

c. S. 746's peer review panels would not have provided any more rigorous or independent review than the outside experts with which NHTSA contracted to review the standard and make recommendations on the best available technology and designs to maximize passenger safety. In fact, without any conflict of interest prohibitions, the peer review panel in S. 746 would be dominated by the regulated industry that would never have made the bold recommendations given to NHTSA.

d. In brief: nothing in S. 746 would have made passenger airbags safer for children.

Auto safety regulations such as child safety seats, head impact protection, airbags and lap/shoulder belt installation have saved hundreds of thousands of lives. Airbags have already saved more than 4,000 lives and are expected to save about 3,000 lives each year when all vehicles have them, in addition to preventing tens of thousands of injuries. The automobile industry fought against NHTSA's occupant restraint safety standard for 25 years beginning in 1970. Manufacturers chose cheaper designs for airbags that failed to protect children not because the NHTSA standard required it, but in order to cut their costs.

We agree with Mr. Graham that deaths and injuries of out-of-position children due to airbags was a preventable tragedy. But the record clearly shows that responsibility for not installing airbags that would have prevented these deaths rests squarely on the auto manufacturers.

To correct the record on NHTSA's fuel economy rulemaking:

1. **Fuel Economy Has Improved Through Better Technology, not a Reduction in Safety**

Since 1974, new car fuel economy has increased by 100% through the use of technology without restricting consumer choice or reducing safety. Today consumers have far safer and more fuel efficienct vehicles to chose from in all size classes. In 1994, we saved over 3.0 million b/d of gasoline and 41,000 lives annually due respectively to CAFE and safety standards that have doubled and fatality rates that have decreased by 50% since 1974.

Technology enabled us to double CAFE from 1975 by 1985 and technology will enable us to redouble CAFE. In 1975, cars had carburetors, 3-speed automatic transmissions and poor aerodynamics. By 1985 cars had fuel injection, 4-speed automatic transmission, good aerodynamics and more efficient engines. By 2005, cars will have electronically controlled 5-speed automatic or continuously variable transmissions, tuned intake manifolds, sleeker aerodynamics, lean burn engines with variable valve timing, reduced friction technology, and some new engines. Increased use of strong, lightweight materials will increase fuel economy themselves and will permit the use of smaller engines for further fuel economy gains.

2. **CAFE Improvements Come From Technology Not Small Cars**

When Congress passed the first fuel economy standards (CAFE) in 1975, the auto industry said it would "outlaw full-size sedans and station wagons [Chrysler]", "require all sub-compact vehicles" and "place hardships on Americans who want and need larger cars [Ford]", and "restrict availability of 5 and 6 passenger cars regardless of consumer needs [GM]."[1] These 1975 charges were nothing more than scare tactics. In fact CAFE doubled while large cars stayed on the road. In 1975, 14.3% of the fleet was large cars; in 1994, 13.6% of the fleet is large cars.

Of the 14.2 MPG gain in CAFE from 14 MPG in 1974 to 28.2 MPG in 1994, 12.4 MPG or 87% results from technological improvements to passenger cars. The increase in CAFE due to weight loss from 1974 was 1.6 MPG or 11.5% and this weight loss came out of very large cars, not smaller cars.[2] Only 0.2 MPG or 1.4% of the improvement came from consumers buying

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[1]Ford testified before Congress:

> [T]his proposal would require a Ford product line consisting of either all sub-Pinto-sized vehicles or some mix of vehicles ranging from a sub-sub-compact to perhaps a Maverick. This would place definite hardships on the many Americans who legitimately want and need larger cars to meet their personal requirements.

Chrysler predicted even more dire results:

> In effect, this bill would outlaw a number of engine lines and car models, including most full-size sedans and station wagons. It would restrict the industry to producing subcompact-size cars-or even smaller ones.

General Motors echoed Chrysler's predictions:

> This legislation would have the effect of placing restrictions on the availability of 5 and 6 passenger cars--regardless of consumer needs or intended use of vehicle. It is not only an unjustified interference with individual freedom, but an extreme and unusual way for a free society to achieve its goals.

[2]GAO Report to Congressional Requesters, "Have Automobile Weight Reductions Increased Highway Fatalities?", October 1991, PEMD-92-1

smaller cars. The virtual elimination of the mini-compact car which went from 11.4% of the market in 1974 to 0.3% in 1994 shows that tighter CAFE standards do not necessitate small cars.

The 14.2 MPG improvement since 1974 is all the more remarkable because 2.8 MPG was lost due to tuning engines for faster acceleration times between 1981 and 1994. If engine performance improvements had been used for CAFE gains instead of faster acceleration, the 1994 CAFE would have been 31.0 MPG and a gain of 17.0 MPG with 15.2 MPG or 89% coming from technological improvements.

3. **Safety & CAFE Do not Conflict With Laws of Physics**

For a given population of present cars, the laws of physics do not command a relationship between CAFE and levels of safety. The safety of vehicles has been demonstrated to be easily improved from current levels with significant weight reductions. Safety is related to structural crashworthiness and occupant protection design technology, while fuel economy is related to engine and transmission efficiency, power to weight ratio, acceleration performance, drag coefficient, materials choice and vehicle packaging (whether an efficient design such as front wheel drive is used).

By using advanced safety features, small cars can be made as safe or safer than large cars. The laws of physics do not say small cars cannot be made safe; they just say good engineering must be used to make any car safe. Indeed the safest cars ever built were small cars, the Research Safety Vehicles built by the Department of Transportation in the late 1970's that used advanced materials and design to make cars lighter while retaining their size and improving both their fuel economy and safety. Many smaller cars today with airbags will outperform larger cars without airbags in vehicle to vehicle crashes.

The basic principles for designing safe, fuel efficient cars was recognized by Dr. William Haddon, the first head of the National Highway Traffic Safety Administration (then known as the National Highway Safety Bureau) and later president of the Insurance Institute for Highway Safety, when he said.

> "Car size - not car weight - is a critical parameter in terms of occupant protection. Since fuel economy is influenced much more by weight than by size, it should be possible to make cars that are of adequate size to protect their occupants (and that have respectable fuel economy as well) by increasing the use of lightweight materials. In this regard, it is worth noting that many of the newer intermediate-size cars have substantially better fuel economy than many of the smallest cars of only a few years ago. (Testimony of Dr. William Haddon, Jr., president, Insurance Institute for Highway Safety, House Committee on Science and Technology, November 1982.)"

"For vehicles using the same roads these relationships suggest a crashworthiness design concept for intervehicular crashes that regards increases in vehicle size as primarily protective, and increases in vehicle weight as primarily hostile, indicating the desirability of relatively sizeable but not heavy vehicles. ("Relationship Between Car Size, Car Weight, and Crash Injuries in Car-to-Car Crashes," William Haddon, B. O'Neill, H. Joksch, IIHS, July 1974.)"

The laws of physics do say motorcycles, pedestrians and all other vehicle occupants would be safer if very large cars were made lighter. The extra weight in large cars offers no safety benefits to their occupants but makes these large vehicle more dangerous when they strike other vehicles and people. By reducing the weight of present large cars while retaining their size, the laws of physics say we will save lives, gasoline and the environment.

4. **Light Truck Fuel Economy Can Be Improved Through Technology**

The same technologies used to improve passenger car fuel economy have similar applications in light trucks. Thus more efficient engines, technologies to reduce friction and pumping losses, materials substitution, and better aerodynamics can all be used in trucks and vans. Light truck and van fuel economy can be readily improved because more technology remains to be used than in passenger cars. For example, multi-point fuel injection is used in nearly 70% of the 1994 new car fleet but only 35% of the light truck and van fleet while multi-valve engines were found in 45% of 1994 cars but only 4% of light trucks and vans. Some technologies such as diesel engines may well have greater use in trucks than in cars due to consumer experience with the technology.

When the Environmental Protection did its last assessment of best in class technology for light trucks in 1990, it found that the top five trucks in each weight class had 20% better fuel economy than the average truck yet had substantially the same performance in terms of top speed and payload. The average fuel economy for the best five in class was 25.2 mpg versus 21.0 for the average truck. If every truck today got the same fuel economy as the best truck in its weight class in 1990, the average light truck CAFE would be 25.9 mpg. Note that best in class analysis is based on no change in sales mix so whatever number of 8500 pound full-size pickups are sold is fixed at that number with no mix shift.

Industry arguments that increased CAFE standards for light trucks will outlaw many large trucks and vans are no more true today than were its arguments in 1975 that CAFE standards would outlaw large cars and station wagons. CAFE standards made large cars better and more fuel efficient. However, industry arguments made in the early 1970's to lift the excise tax on light trucks on the grounds that they are used for the substantially the same purposes as cars and should be treated the same as cars is more telling.[3]

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[3]See e.g., Testimony of Franklin Kreml, President of American Automobile Manufacturers Association, Hearings on Revenue Act of 1971 Before Sen. Finance Comm., 578 (Oct. 1971). "Increasingly, these light duty trucks are becoming a second car for an ever-growing segment of the American population and compete directly with the passenger car."

5. **NHTSA Has Produced Landmark Regulatory and Cost-Benefit Analyses and Reports on the CAFE Program Showing Multiple Benefits for the Nation**

Mr. Graham apparently is not aware of the numerous analysis prepared by NHTSA of the CAFE standards beginning in 1976. The agency spent millions of dollars each year from 1976 to 1982 with the expert assistance of the Volpe Transportation Center preparing detailed analyses by factory and component of company's capability and cost to comply with various fuel economy numbers (prior to issuance of the 1980-1985 standards in 1977 and in preparation for issuance of LTV standards each year). In addition, in 1979, the agency conducted for the White House a major review and reanalysis of the costs and benefits. Further, every year since 1978 the NHTSA has prepared a fuel economy report to the Congress. In fact, NHTSA has been recognized for its expert work and analyses in this area.

As to greater incentives to purchase fuel efficient vehicles, Mr. Graham is also off the mark. The agency has no statutory authority to provide such incentives. However, the Department of Transportation did prepare various sets of alternatives over the years for the Congress to consider, including substantially increasing gas prices. This never occurred because it is an unpopular idea with the public.

Finally, the value of the CAFE program goes far beyond the costs and benefits to car drivers as the Department has documented on many occasions.

CAFE standards have advanced major national policies. These include enhanced national security through reduced dependence on imported oil; significantly reduced fuel consumption and lowered greenhouse gas emissions; improved U.S. balance of trade and balance of payments resulting from reduced oil imports; reduced inflationary pressure; lessened dependence of the U.S. economy on foreign petroleum supplies; reduced air pollution by decreasing evaporative emissions; and stimulated substantial innovation in automotive design and production technology. There can be little doubt that the CAFE standards, by decreasing demand for petroleum, helped break OPEC's ability to fix high oil prices in the 1980's.

Growth in the number of vehicles on the road from 133 million in 1975 when EPCA was passed to 203 million today has outstripped gains in fuel efficiency (which have not been increased since 1985 for cars and only a few mpg for LTV's since 1980) so that the nation relies more on imported oil than ever. When EPCA was passed in 1975, the US imported 6.5 million b/d of oil out of 16.5 million used with cars and light trucks consuming 6.0 million b/d. By 1997, the US imported 9.2 million b/d to meet the demand of 17.3 million b/d with cars and light trucks consuming 7.1 million b/d.

Response By Professor John D. Graham to Comments Submitted by Ms. Joan Claybrook

Ms. Claybrook's comments on my testimony merit serious consideration because of her significant career of accomplishment in public service and consumer advocacy. At the same time, readers should be aware that Ms. Claybrook was Administrator of the National Highway Traffic Safety Administration from 1977 to 1980, a period when NHTSA made some very controversial decisions about airbags and fuel economy issues. She is not a disinterested commentator about what happened during this period of American history and thus I appreciate the opportunity to respond to her comments.

The Airbag Issue

Ms. Claybrook argues that NHTSA adopted a performance standard, subjected this standard to technical evaluation, and allowed vehicle manufacturers to make the design choices. She acknowledges that airbags have not performed as well as expected but attributes this outcome to poor ("greedy") decision making on the part of most vehicle manufacturers. She argues that if manufacturers had chosen her preferred airbag designs (e.g., dual inflation capabilities and top-mounted placements) children would have been protected from severe injury.

Complicating Facts

1. NHTSA'S 1980 RISK ASSESSMENT CONCERNING CHILDREN WAS ERRONEOUS, WAS NEVER SUBJECTED TO THE INDEPENDENT PEER REVIEWED CALLED FOR IN S. 746, AND LAYED THE GROUNDWORK FOR UNSAFE REGULATORY POLICY.

In 1980 engineers from GM and Honda prepared risk assessments of the airbag that reached the same conclusion: state-of-the-art passenger airbag designs are likely to pose a significant danger to children seated in the front seat.[1] The leadership of NHTSA was skeptical of these claims and thus NHTSA prepared its own risk assessment.[2] The authors of NHTSA's assessment concluded in 1980: "The analysis shows that, on balance, air bags will provide substantial crash protection to otherwise unrestrained children and adults in crashes."[3]

In a July 1980 report prepared for distribution to Congress and the public, NHTSA referred to GM's "theory" of harm to children as "somewhat speculative" and instead offered reassurance: "In conclusion, there is not only a substantial net societal benefit from having air bags in passenger cars, but there is a net benefit even for the specific class of occupants considered here – infants and small children in the front seat."[4] It is important to recognize that this claim was not restricted to any particular type of passenger airbag design but was a general claim about passenger airbag technology under consideration in 1980. NHTSA went on to say that "Those benefits will be further enhanced by the special attention that the

[1] F Montalvo, RW Bryant, HJ Mertz, " Possible Positions and Posture of Unrestrained Front Seat Children at Instant of Collision," Eighth International Technical Conference on Experimental Safety Vehicles, Wolfsburg, Germany, NHTSA, U.S. DOT, 1980, pp. 336-341. H Takeda, S Kobayshi, "Injuries to Children From Airbag Deployment," Eighth International Technical Conference on Experimental Safety Vehicles, Wolfsburg, Germany, NHTSA, U.S. DOT, 1980, pp.325-332.

[2] JD Graham, Auto Safety: Assessing America's Performance, Praeger, Westport, CN, 1989.

[3] R.J. Hitchcock, CE Nash, "Protection of Children and Adults in Crashes of Cars with Automatic Restraints," Eighth International Technical Conference On Experimental Safety Vehicles, Wolfsburg, Germany, NHTSA, U.S. DOT, 1980, pp. 317-325.

[4] U.S. Department of Transportation, Automobile Occupant Crash Protection: Progress Report Number 3, NHTSA, July 1980, p.75.

automobile manufacturers are paying to the protection of small children in the design of these systems."[5] Thus, features such as dual-inflation and vertical deployment were considered by NHTSA to be refinements to what was already an effective safety device for children.

What we now know is that the 30 million passenger airbags sold to American motorists from 1990 to 1997 – designs similar to those analyzed by NHTSA in 1980 -- have caused a net increase in fatality risk to children in the front seat.[6] There was no solid scientific basis for NHTSA's reassuring claims, particularly the ill-founded notion that many unrestrained infants and small children would be saved by passenger airbags. NHTSA made these erroneous claims about passenger airbags at international technical meetings where the papers presented are not peer reviewed for technical quality prior to presentation or publication, as is typical at peer-reviewed journals such as the *New England Journal of Medicine* or the *Journal of the American Medical Association*. More importantly, NHTSA never subjected its risk assessment of airbags and child safety to the procedures for independent peer review that are layed out in S. 746 and that are typical in some regulatory programs at the Food and Drug Administration and the Environmental Protection Agency.[7]

Ms. Claybrook oversimplifies the technical challenge of protecting unrestrained children by suggesting that dual-inflation systems or top-mounted systems would have protected children. For example, the first-stage deployment in a dual-stage system would be less forceful in lower-speed collisions but the injuries to children might still be quite severe if the child's head or neck is within an inch of the airbag housing when the bag deploys – as can be expected to occur when pre-crash braking causes unrestrained children to be thrown forward near the airbag housing prior to deployment. Even vertically-deploying airbags can harm children if the child's head is hovering over the top of the instrument panel prior to deployment.

Vehicle manufacturers such as Ford recognize that dual-inflation systems and vertical deployment are not a panacea for the risks to children and are now choosing to supplement dual-staged inflation with advanced technology that will stop airbag deployment entirely if a small child is seated in the front seat ("suppression technology"). Even these advanced technologies can be expected to have a residual error rate (e.g., confusing children and adults) and thus it is recommended that children sit in the rear seat whenever possible.

By dismissing the real danger of airbags to children in 1980, NHTSA created a false sense of security about the safety of children riding in the front seat of a vehicle with a passenger airbag and may have slowed the development of suppression technologies. To its credit, NHTSA has reversed its position on these issues and is now, twenty years later, acknowledging the gravity and complexity of the child safety issue and collaborating with the private sector (insurers, suppliers, and vehicle manufacturers) in efforts to make sure that children are restrained properly in the rear seat. A careful regulatory analysis, such as the one mandated in S. 746, would have caused NHTSA to take a more serious look at steps that could have been taken proactively to protect children from airbag deployment.

2. NHTSA'S PERFORMANCE STANDARD WAS FLAWED BECAUSE IT REQUIRED PROTECTION OF UNBELTED AND BELTED ADULT MALE DUMMIES WITHOUT INCLUDING PERFORMANCE CRITERIA FOR CHILDREN AND SMALL-STATURED ADULTS.

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[5] *Ibid.*

[6] E.R. Braver, SA Ferguson, MA Greene, AK Lund, "Reductions in Deaths in Frontal Crashes Among Right Front Passengers in Vehicles Equipped With Passenger Airbags," *Journal of the American Medical Association*, Vol. 278 (17), 1997, pp. 1437 - 1439.

[7] S. Jasanoff, The Fifth Branch: Science Advisors as Policymakers, Harvard University Press, Cambridge, MA, 1991.

The rationale for performance standards (as opposed to design standards) is that manufacturers should retain the freedom to make choices among technologies that offer an equivalent level of protection to motorists. By issuing a performance standard that required manufacturers to protect large unbelted and belted males without protecting unbelted or belted children (or women), NHTSA encouraged manufacturers to choose among a set of technologies that offered widely varying degrees of protection and risk to motorists of different sizes. While manufacturers are now being sued for risks that resulted from the design choices they made, it is certainly fair to criticize NHTSA for designing a performance standard that permitted airbag technologies with inferior overall safety performance to be marketed to consumers.

Nor did NHTSA take seriously the inherent tradeoff engineers faced in protecting large males and small children in crashes. Even the first-stage of a dual-stage airbag system requires a tradeoff: how much protection should be offered to small children and how much to large adults? In 1977, 1980, and again in 1984, NHTSA regulatory analyses failed to provide a careful risk-benefit analysis of the requirement that large unbelted males be provided the level of protection called for in the performance standard. Once it became clear that this provision was inducing airbag designs that were too powerful for the safety of many children and belted adults, the Canadian government and NHTSA granted permission to manufacturers to depower airbags by 20-30%, at least until more advanced airbags become available.[8]

When a regulator designs a flawed performance standard that permits profit-maximizing firms to install "lousy" and lethal safety technology, the regulator as well as the industry should shoulder some of the responsibility. As a nation, we should learn from this experience by passing legislation that requires agencies to perform careful regulatory analysis and peer review prior to making major rulemaking decisions that will affect public health, safety, and the environment.

Fuel Economy Rules

Ms. Claybrook argues that fuel economy rules have been successful in saving energy and that it is technically feasible to design vehicles that are safer and more fuel efficient. She also argues that NHTSA has performed landmark analyses that cover the costs and benefits of these rules.

Complicating Facts

1. NHTSA'S REGULATORY ANALYSES OF THE FUEL ECONOMY PROGRAM (INCLUDING THE ANNUAL FUEL ECONOMY REPORT TO CONGRESS) HAVE NOT GIVEN SERIOUS ATTENTION TO THE SAFETY CONSEQUENCES OF FUEL ECONOMY RULES.

Previous research published in the peer-reviewed scientific literature has demonstrated one of the perverse consequences of the federal government's fuel economy program: Passenger cars have been downsized by almost 500 - 1,000 pounds, causing cars to be less crashworthy for occupants than they would have been had they not been downsized.[9]

This research was ignored by NHTSA for almost five years until a federal appeals court ordered NHTSA to take the safety issue seriously.[10] To its credit, the agency has reversed course and acknowledged, in a

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[8] JD Graham, SJ Goldie, M Segui-Gomez, KM Thompson, T Nelso, R Glass, A Simpson, LG Woerner, "Reducing Risks to Children in Vehicles with Passenger Airbags," *Pediatrics* (electronic edition), vol. 102(1), July 1998, (www.pediatrics.org/cgi/content/full/102/1/e3).

[9] RC Crandall, JD Graham, "The Effect of Fuel Economy Standards on Automobile Safety," *Journal of Law and Economics*, vol. 32, 1989, pp. 97-118. JD Graham, "The Safety Risks of Proposed Fuel Economy Legislation," *Risk: Issues in Health and Safety*, vol. 3, 1992, pp. 95 – 126. Insurance Institute for Highway Safety, "Comparison Shows Downsizing Plays a Dramatic Role in Occupant Death Rates," *Status Report: Highway Loss Reduction*, March 16, 1991, p. 4.

[10] Competitive Enterprise Institute vs. NHTSA, 956 Fed.2d 321 (D.C. Circuit 1992).

series of technical papers, the incremental safety risks to occupants caused by the downsizing of cars in the 1970s and early 1980s.[11]

2. NHTSA'S FUEL ECONOMY RULES ARE ALSO FLAWED PERFORMANCE STANDARDS BECAUSE SAFETY IS NOT A FEATURE OF THE PERFORMANCE PARAMETERS IN THESE RULES, WHICH MEANS THAT VEHICLE MANUFACTURERS ARE PERMITTED TO COMPLY WITH DESIGNS THAT COMPROMISE THE SAFETY OF VEHICLE OCCUPANTS.

Ms. Claybrook cites Dr. Haddon's research demonstrating that it is technically feasible to design vehicles that are safer and more fuel-efficient. Yet NHTSA's fuel economy rules provide no incentive for manufacturers to comply in that manner or for consumers to demand vehicles that are safer and more fuel-efficient. Instead, NHTSA has issued a series of rules on fuel economy with no attention to safety concerns and without even warning consumers of the adverse safety consequences of purchasing smaller and lighter vehicles. Designing sound regulatory policy requires that careful analysis be performed of tradeoffs between important national goals such as energy efficiency, safety, and environmental protection.[12]

Conclusion

S. 746 has an excellent provision, Section 623(2)C, that requires any "substitution risks" of rules to be considered by regulators when such information is reasonably available to the agency. A "substitution risk" is a significant threat to health, safety, and environment caused by a rule! This single provision, had it been passed by Congress in 1970, might have exerted a significant, pro-safety influence on both NHTSA's airbag rule and NHTSA's fuel-economy rules. Congress would also have been confronted with information about the adverse safety impacts of airbags and fuel economy rules, empowering Congress to design more intelligent statutory directions to NHTSA.

The fact that Ms. Claybrook did not mention Section 623(2)C of S. 746 suggests that she may have missed the entire point of the three examples in my testimony (MTBE, airbags, and fuel economy). Regulators should be expected to behave like competent physicians: Professionals who inform patients of the side effects as well as the benefits of the treatments they prescribe. Citizens have a right to know the risks as well as the benefits of major federal regulations before these regulations are adopted and implemented.[13]

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[11] U.S. DOT, The Effect of Car Size on Fatality and Injury Risk in Single-Vehicle Crashes, NHTSA, Washington, D.C., 1990.

[12] RC Crandall, HK Gruenspecht, TE Keeler, L Lave, Regulating the Automobile, Brookings Institution, Washington, D.C., 1986.

[13] JD Graham, JB Wiener (eds), Risk vs. Risk: Tradeoffs in Protecting Health and the Environment, Harvard Univ. Press, Cambridge, MA, 1995. EW Warren, GE Marchant, "More Good Than Harm: A Hippocratic Oath for Environmental Agencies and Courts," *Ecology Law Quarterly*, vol. 20, 1993, pp. 379-440.

United States General Accounting Office

GAO

Report to the Committee on Governmental Affairs, U.S. Senate

May 1998

REGULATORY REFORM

Agencies Could Improve Development, Documentation, and Clarity of Regulatory Economic Analyses

GAO/RCED-98-142

GAO
United States
General Accounting Office
Washington, D.C. 20548

Resources, Community, and
Economic Development Division

B-279614

May 26, 1998

The Honorable Fred Thompson
Chairman
The Honorable John Glenn
Ranking Minority Member
Committee on Governmental Affairs
United States Senate

This report responds to your request that we describe the extent to which federal agencies are incorporating the best practices set forth in the Office of Management and Budget's (OMB) guidance for preparing economic analyses in accordance with Executive Order 12866 and the Unfunded Mandates Reform Act of 1995. The report discusses the development, documentation, and use of economic analyses in agencies' regulatory decision-making and contains recommendations to the Director, OMB. The recommendations are designed to enhance the quality and credibility of agencies' economic analyses.

We are sending copies of this report to other appropriate congressional committees; the Director, OMB; the Secretaries of Agriculture and Transportation; the Administrators of the Environmental Protection Agency and the Occupational Safety and Health Administration; and the Commissioner of the Food and Drug Administration. Copies are available to others upon request.

If you or your staff have any questions, please call me at (202) 512-6111. Major contributors to this report are listed in appendix I.

Peter F. Guerrero
Director, Environmental
Protection Issues

Executive Summary

Purpose

The last 20 years have seen enormous growth in the number and scope of federal regulations. According to the Office of Management and Budget (OMB), although these regulations have improved public health and safety and environmental quality, their costs are high. In 1996, OMB estimated the costs of federal regulations at $200 billion annually and the benefits at $300 billion. To control the costs of regulation, the administration has issued executive orders, including Executive Order 12866, and the Congress has enacted laws, including the Unfunded Mandates Reform Act of 1995 (UMRA). These orders and laws require federal agencies to prepare and use economic analyses—also known as regulatory impact analyses—to assess the benefits and costs of proposed actions before promulgating regulations. These analyses are intended to inform and improve the regulatory process by identifying the likely costs and benefits of feasible alternatives. An interagency group convened by OMB has developed guidance for implementing Executive Order 12866 and UMRA. This guidance sets forth best practices for preparing economic analyses.

To assist the Senate Committee on Governmental Affairs in carrying out its regulatory oversight responsibilities, the Chairman and Ranking Minority Member asked GAO to describe (1) the extent to which federal agencies' economic analyses incorporate the best practices set forth in OMB's guidance and (2) the agencies' use of these analyses in regulatory decision-making.

Background

In 1993, President Clinton issued Executive Order 12866, the most recent of several executive orders requiring federal agencies to conduct economic analyses when developing regulations. Under the order, an agency must conduct an economic analysis of a planned regulation and alternatives to it for an economically significant rule—one that may have an annual effect on the economy of $100 million or more. In 1995, the Congress enacted UMRA, which imposes a statutory requirement on federal agencies to conduct benefit-cost analyses of planned regulations. UMRA's scope differs slightly from the scope of the executive order. Specifically, the act requires analyses for proposed or final rules that may result in the expenditure of $100 million or more in any one year, either by state, local, and tribal governments in the aggregate or by the private sector alone. Most recently, Senators Thompson and Levin introduced a bill (S. 981) that would, among other things, require executive summaries and peer reviews for economic analyses. In the past, GAO has recommended executive summaries for economic analyses to enhance their clarity, and peer reviews to enhance their quality and credibility.

In 1996, OMB issued a document describing best practices for preparing economic analyses under Executive Order 12866 and UMRA. These best practices include considering the most important alternative approaches to the problem, analyzing the benefits and costs of these alternatives, and fully disclosing information about the analysis, including the underlying uncertainties and assumptions.

GAO included in this review all economically significant proposed and final rules issued between July 1996 and March 1997 that addressed environmental, health, and safety matters. As a result, GAO reviewed the economic analyses used in promulgating 20 regulations by five agencies—the Departments of Agriculture and Transportation, the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA) within the Department of Health and Human Services, and the Occupational Safety and Health Administration (OSHA) within the Department of Labor. Nine of these regulations involved potential expenditures large enough to bring the regulations within the scope of UMRA.

Results in Brief

Some of the 20 economic analyses that GAO reviewed did not incorporate the best practices set forth in OMB's guidance. For example, 5 of the 20 analyses did not discuss alternatives to the proposed regulatory action, 6 did not assign dollar values to benefits, and 1 did not assign dollar values to costs—all of which are practices recommended by the guidance. OMB's guidance gives agencies the flexibility to decide how thorough their economic analyses should be. At the same time, the guidance stresses the importance of fully disclosing the reasons for omissions, gaps, or other limitations. Although GAO found many instances in which best practices were not followed in the analyses, the reason for not following was disclosed in only one instance. In addition, eight of the economic analyses did not include an executive summary that could help the Congress, decisionmakers, the public, and other users quickly identify key information addressed in the analyses. Finally, only 1 of the 20 analyses received an independent peer review. Because Executive Order 12866 and UMRA establish nearly identical requirements for economic analyses and because agencies typically use the same analyses to comply with both when UMRA is applicable, GAO's findings reflect the extent to which the nine analyses called for under UMRA satisfy the act's as well as the executive order's requirements for economic analyses.

According to agency officials, economic analyses play a valuable role in regulatory decision-making. Twelve of the 20 analyses were used to help identify the most cost-effective of several similar alternatives or to cost-effectively implement health-based regulations. Seven other analyses were used to define a regulation's scope and implementation date, document and defend regulatory decisions, or reduce a health risk at a feasible cost. One analysis played almost no role in decision-making because, according to agency officials, the authorizing statute was so prescriptive that the agency was left with virtually no discretion in developing the implementing regulation.

Principal Findings

Some Economic Analyses Lacked Full Disclosure

For 15 of the 20 regulations that GAO reviewed, the agencies included at least one alternative to the proposed action, but in some instances, the discussion of the alternative was limited. For the five remaining regulations, no evidence was available to show that the agencies had considered alternatives. Agency officials stated that for these five analyses, the agencies either had considered alternatives but had not included them in the analyses or had not considered alternatives at all. Agency officials' reasons for not addressing or considering alternatives included the specificity of the authorizing legislation or the need to issue regulations quickly. Although OMB's guidance states that these can be legitimate reasons for agencies to limit the consideration of alternatives, the guidance also states that even when such limitations apply, agencies should provide some analysis of alternatives to provide decisionmakers with information for judging the consequences of statutory constraints.

Nineteen of the economic analyses assigned dollar values to some costs, and 14 assigned dollar values to some benefits. Similarly, 15 of the analyses discussed the uncertainties associated with the estimates of benefits and costs, but none of the remaining 5 analyses explained why they did not discuss the uncertainty associated with the estimated benefits and costs.

The clarity of the 20 analyses varied, making it difficult at times to determine where or whether elements of OMB's guidance were discussed. Eight of the analyses did not include an executive summary. GAO has previously recommended that EPA's analyses, and S. 981 would require that

all agencies' analyses, contain an executive summary that clearly describes the results of the economic analysis and the key points of the analysis. Only one of the 20 analyses underwent an independent peer review. GAO has previously stated that EPA should use peer review to help ensure the quality and credibility of an analysis. While a similar requirement for peer review for all agencies would entail some costs, as OMB has observed, peer review by independent experts—either internal or external to the agency—could be tailored to reflect the importance, sensitivity, and innovativeness of the analysis and of the associated regulatory decision.

Agencies Often Used Economic Analyses to Identify Cost-Effective Approaches

According to agency officials, the analyses were most frequently used to identify the most cost-effective approach within a fairly narrow range of options. For example, EPA used its economic analysis for a rule on marine engine emissions to examine the costs of different emission levels and to select the most cost-effective level. Four other analyses were used primarily to help agencies better define a rule's coverage or to determine when to implement a rule. For example, EPA's economic analysis for a proposed rule on procedures for testing emissions from motor vehicles incorporated data provided by the automobile industry and led to revisions that gave the industry additional time to implement the final rule. Two analyses were used principally to help agencies document or justify decisions that they had already made. According to agency officials, specific statutory requirements limited their discretion in making regulatory decisions and were a primary reason why economic analyses played a limited role in regulatory decision-making. For example, the Clean Air Act of 1990 directed EPA to review and revise its regulations on motor vehicle testing to better reflect actual driving conditions.

Recommendations

To strengthen the clarity and credibility of the economic analyses required for regulatory decision-making, GAO recommends that the Director, Office of Management and Budget, amend the Office's guidance to include additional elements, two of which are proposed in S. 981. Specifically, GAO recommends that the guidance be amended to provide that economic analyses should

- address all of the best practices identified in OMB's guidance or state the agency's reasons for not addressing them;
- contain an executive summary that briefly and concisely (1) identifies all benefits and costs—both those that can be described quantitatively and those that can be described qualitatively; (2) describes the range of

uncertainties associated with the benefits and costs; and (3) compares the reasonable alternatives considered by the agency; and
- undergo an appropriate level of internal or external peer review by independent experts and state the agency's basis for selecting that level.

Agency Comments

GAO provided a draft of this report to the Office of Management and Budget; the Departments of Agriculture and Transportation, EPA, FDA, and OSHA. GAO received comments from all of these agencies except OSHA, which informed GAO that it had no comments on the draft. The agencies generally agreed with the information presented in the report and concurred with GAO's recommendations calling for economic analyses to address OMB's best practices and to include an executive summary. Although the agencies agreed with GAO that peer review can be beneficial, they suggested that GAO clarify and expand its discussion and recommendation on this issue to more clearly acknowledge that agencies should have discretion in selecting an appropriate level of peer review. FDA urged GAO to delete this recommendation, maintaining that such a requirement would likely make it impossible for the agency to meet other statutory responsibilities. GAO has revised the discussion and recommendation on peer review to clarify that agencies should have such discretion but should also state their basis for selecting a given level of peer review. The agencies offered several technical and/or clarifying comments, which GAO incorporated throughout the report as appropriate.

Contents

Abbreviations

DOT	Department of Transportation
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
OMB	Office of Management and Budget
OSHA	Occupational Safety and Health Administration
UMRA	Unfunded Mandates Reform Act
USDA	U.S. Department of Agriculture

Chapter 1

Introduction

Each year, federal agencies establish or revise rules and regulations designed to promote, among other purposes, public health and safety and environmental quality. According to the Office of Management and Budget (OMB), these regulations produce great benefits but also impose great costs. In 1997, OMB estimated annual benefits of about $300 billion and annual costs of about $200 billion for federal regulations in effect at that time. Because of the magnitude of these estimated values, as well as the effect of the rules on individuals, firms, industries, and government agencies, the executive branch and the Congress require federal agencies to prepare and use economic analyses—also called regulatory impact analyses—in their regulatory decision-making process. These analyses are intended to inform and improve the regulatory process by estimating the likely benefits and costs of feasible alternatives and identifying the alternative that has the greatest net benefits (benefits minus costs). Although the weight that the analyses should receive in the decision-making process is the subject of some disagreement, the analyses themselves are generally recognized as an important and useful tool.

Executive Branch's Efforts to Improve the Regulatory Process

Since 1971, a series of executive orders and directives by OMB have required federal agencies to consider the benefits and costs associated with individual regulations. In February 1981, President Reagan issued Executive Order 12291, which required federal agencies to prepare economic analyses identifying the benefits, costs, and alternatives for all proposed and final major rules that the agencies issued. A major rule was defined as any regulation that was likely to result in (1) an annual effect on the national economy of $100 million or more; (2) a major increase in costs or prices for consumers, industries, governments, or geographic regions; or (3) significant adverse effects on competition, employment or investments, productivity, innovation, or the international competitive position of U.S. firms. In September 1993, President Clinton issued Executive Order 12866, replacing Executive Order 12291 and directing federal agencies to assess benefits, costs, and alternatives for all economically significant regulatory actions. Under the order, an economically significant regulatory action is one that is likely to result in a regulation that may have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities.

Both executive orders designated OMB as the reviewer of proposed regulations and of the economic analyses supporting them. OMB developed

guidance for implementing both orders. Shortly after President Clinton issued Executive Order 12866, OMB convened an interagency group to review the state of the art for economic analyses. The group was co-chaired by a Member of the Council of Economic Advisers and included representatives of all major regulatory agencies. Over 2 years, the group compiled best practices for preparing economic analyses, which OMB published in January 1996 as guidance for implementing the executive order.

OMB's guidance emphasizes that an economic analysis should provide information to allow decisionmakers to determine that

- there is adequate information indicating the need for and consequences of the proposed action;
- the potential benefits to society justify the potential costs, recognizing that not all benefits and costs can be described in monetary or even quantitative terms, unless otherwise prohibited by statute;
- the proposed action will maximize net benefits to society, unless otherwise prohibited by statute;
- when a statute requires a specific regulatory approach, the proposed action will be the most cost-effective; and
- the agency's decision is based on the best reasonably obtainable scientific, technical, economic, and other information.

The Environmental Protection Agency (EPA) and the Department of Transportation (DOT) developed additional guidance to address unique issues their agencies may face in preparing their economic assessments.

Congressional Efforts to Improve the Regulatory Process

Since the late 1970s, the Congress has taken a number of steps to improve the regulatory process and control the costs of regulation. For example, the Congress has enacted several statutes to reduce the costs and burdens of federal regulations, including the Paperwork Reduction Act of 1980, the Regulatory Flexibility Act, the Small Business Regulatory Enforcement Fairness Act of 1996, and the Unfunded Mandates Reform Act of 1995 (UMRA).

UMRA requires agencies to prepare benefit-cost and other analyses—unless prohibited by law—for any regulations imposing mandates likely to result in expenditures of $100 million or more in any one year either by state, local, and tribal governments in the aggregate or by the private sector alone. Although UMRA's scope and requirements differ from Executive

Order 12866's, both authorities' provisions on economic analysis are very similar. Accordingly, OMB's guidance for implementing the executive order states that "the economic analysis that the agency prepares should also satisfy the requirements of the Unfunded Mandates Reform Act."

The Congress has also considered—but not enacted—other initiatives to reform the regulatory process. Some of the more comprehensive initiatives proposed to establish regulatory budgets; create deadlines for phasing out regulations, programs, and agencies; revise and expand the judicial review of regulatory actions; and require the federal government to reimburse state and local governments for the costs they incur in complying with federal regulations.

Currently, the Congress is considering S. 981, the Regulatory Improvement Act of 1998. Intended to improve the quality of regulatory decision-making, the bill would, among other things, codify many of the requirements of Executive Order 12866 and establish a requirement for independent peer reviews (critical evaluations of technical work products by independent experts) of economic analyses. To make the regulatory process clearer, or more "transparent," to the public, the bill would require agencies to prepare executive summaries for their economic analyses that would succinctly present, among other things, (1) the benefits and costs expected to result from the rule; (2) the benefits and costs of reasonable alternatives considered by the agency; and (3) the key assumptions and scientific or economic information upon which the agency relied.

Related GAO Reviews

GAO has issued a number of reports on economic analyses, peer review, and unfunded mandates. In 1984, we issued a report on EPA's use of economic analyses.[1] To help agency decisionmakers, we recommended that economic analyses include executive summaries that identify (1) all benefits and costs—that is, both those that can be described quantitatively and those that can be described qualitatively; (2) the range of uncertainties associated with the benefits and costs; and (3) a comparison of all feasible alternatives. In April 1997, we revisited this issue and made a similar set of recommendations to EPA to help agency decisionmakers and the Congress better understand the implications of proposed regulatory actions.[2] In September 1997, we issued a report on the economic analyses prepared by

[1]Cost-Benefit Analysis Can Be Useful in Assessing Environmental Regulations, Despite Limitations (GAO/RCED-84-62, Apr. 6, 1984).

[2]Air Pollution: Information Contained in EPA's Regulatory Impact Analyses Can Be Made Clearer (GAO/RCED-97-38, Apr. 14, 1997).

the Consumer Product Safety Commission in which we recommended that the Commission develop procedures to ensure that its analyses are comprehensive and reported in sufficient detail.[3]

In 1996, we issued a report on EPA's implementation of peer review,[4] in which we recommended wider, more consistent implementation of the agency's policy on peer review to enhance the quality and credibility of the agency's decision-making. In response to questions raised at a March 1997 hearing on this issue, we said that, given the uncertainties associated with predicting the future economic effects of various regulatory alternatives, peer review would help to provide the rigorous independent review of economic analyses needed to enhance the quality, credibility, and acceptability of both the economic analyses and the associated regulatory decisions.

In 1998, we issued a report on the Unfunded Mandates Reform Act of 1995.[5] That report concluded that UMRA has had little effect on agencies' rulemaking actions because the act's requirements (1) do not apply to many large rulemaking actions; (2) allow agencies not to take certain actions if the agencies determine that the actions are duplicative or infeasible; and (3) direct agencies to take actions that they are already required to take.

Most recently, we provided testimony on S. 981.[6] In that testimony, we concluded that the passage of S. 981 would provide a statutory foundation for such principles as openness, accountability, and sound science in rulemaking. We cautioned, however, that our reviews of current regulatory requirements suggest that even if S. 981 becomes a law, the Congress will need to carefully oversee its implementation to ensure that the principles embodied in the bill are faithfully implemented.

Objectives, Scope, and Methodology

To assist the Senate Committee on Governmental Affairs in carrying out its regulatory oversight responsibilities, the Chairman and the Ranking Minority Member asked GAO to describe (1) the extent to which federal

[3]Consumer Product Safety Commission: Better Data Needed to Help Identify and Analyze Potential Hazards (GAO/HEHS-97-147, Sept. 29, 1997).

[4]Peer Review: EPA's Implementation Remains Uneven (GAO/RCED-96-236, Sept. 24, 1996).

[5]Unfunded Mandates: Reform Act Has Had Little Effect on Agencies' Rulemaking Actions (GAO/GGD-98-30, Feb. 4, 1998).

[6]Regulatory Reform: Comments on S. 981—The Regulatory Improvement Act of 1998 (GAO/T-GGD/RCED-98-95, Feb. 24, 1998).

agencies' economic analyses incorporate the best practices set forth in OMB's guidance and (2) the agencies' use of these analyses in regulatory decision-making.

To describe the extent to which federal agencies' economic analyses incorporate the best practices set forth in OMB's guidance, we reviewed all analyses prepared for "economically significant"[7] proposed and final rules issued between July 1996 and March 1997 that addressed environmental, health, and safety matters. Using these selection criteria, we identified 20 proposed and final rules promulgated by five agencies. Nine of these rules were expected to impose mandates likely to result in expenditures of $100 million or more annually either by state, local, and tribal governments in the aggregate or by the private sector; therefore, the agencies also used these analyses to satisfy UMRA's requirements for economic analyses. Table 1.1 presents the rules, by agency, together with their dates of publication in the Federal Register and the stages in rulemaking when the economic analyses were published.

Table 1.1: Economically Significant Rules Involving Environmental, Health, or Safety Issues Promulgated Between July 1, 1996 and March 30, 1997

Department or agency and office	Title of rule	Date published in the Federal Register	Rulemaking stage
Department of Agriculture			
Farm Service Agency	Conservation Reserve Program—Long-Term Policy	Sept. 23, 1996 Feb. 19, 1997	Proposed Final
Natural Resources Conservation Service	Environmental Quality Incentives Program	Oct. 11, 1996 May 22, 1997	Proposed Final
Animal and Plant Health Inspection Service	Karnal Bunt Disease: Domestic Plant-Related Quarantine	Aug. 2, 1996 Oct. 4, 1996	Proposed Final
Food Safety and Inspection Service	Pathogen Reduction: Hazard Analysis and Critical Control Point (HACCP) Systems[a]	July 25, 1996	Final
Department of Health and Human Services			
Food and Drug Administration	Food Labeling: Nutrition Labeling, Small Business Exemption	Aug. 7, 1996	Final
	Medical Devices: Current Good Manufacturing Practice (CGMP)	Oct. 7, 1996	Final

(continued)

[7]Under Executive Order 12866, an economically significant regulatory action is a substantive action by an agency that is likely to result in a regulation that may have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy; a sector of the economy; productivity; competition; jobs; the environment; public health or safety; or state, local, or tribal governments or communities.

Department or agency and office	Title of rule	Date published in the Federal Register	Rulemaking stage
	Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents[a]	Aug. 28, 1996	Final
	Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed	Jan. 3, 1997 June 5, 1997	Proposed Final
Department of Labor			
Occupational Safety and Health Administration	Occupational Exposure to Methylene Chloride[a]	Jan. 10, 1997	Final
Environmental Protection Agency			
Solid Waste and Emergency Response	Financial Assurance Mechanisms for Local Government Owners and Operators of Municipal Solid Waste Landfill Facilities	Nov. 27, 1996	Final
Air and Radiation	Regulation of Fuels and Fuel Additives; Certification Standards for Deposit Control Gasoline Additives[a]	July 5, 1996	Final
	Acid Rain Programs Nitrogen Oxides Emission Reduction Program[a]	Dec. 19, 1996	Final
	Motor Vehicle Emissions Federal Test Procedure Revisions[a]	Oct. 22, 1996	Final
	National Ambient Air Quality Standards for Ozone[b]	Dec. 13, 1996 July 18, 1997	Proposed Final
	National Ambient Air Quality Standards for Particulate Matter[b]	Dec. 13, 1996 July 18, 1997	Proposed Final
	Emission Standards for Locomotives and Locomotive Engines[a]	Feb. 11, 1997	Proposed
	Air Pollution Control; Gasoline Spark-Ignition Marine Engines: New Nonroad Compression-Ignition and Spark-Ignition Engines, Exemptions[a]	Oct. 4, 1996	Final
Pollution Prevention and Toxics	Lead: Requirements for Lead-Based Paint Activities in Target Housing and Child-Occupied Facilities	Aug. 29, 1996	Final

(continued)

Department or agency and office	Title of rule	Date published in the Federal Register	Rulemaking stage
Department of Transportation			
National Highway Traffic Safety Administration	Federal Motor Vehicle Safety Standards; Child Restraint Systems; Tether Anchorages for Child Restraint Systems; Child Restraint Anchorage System[a]	Feb. 20, 1997	Proposed
	Federal Motor Vehicle Safety Standards: Occupant Crash Protection (Air Bag Depowering)	Jan. 6, 1997 Mar. 19, 1997	Proposed Final

[a]Rule also triggers UMRA's requirement for economic analysis. [b]EPA maintains that it was not required to prepare economic analyses under UMRA for these rules even though they come within UMRA's scope because (1) UMRA requires the preparation of economic analyses for covered rules unless otherwise prohibited by law; (2) the Clean Air Act prohibits EPA from considering costs in setting these health-based standards; and (3) the Conference Report for UMRA states that if the agency is prohibited by law from considering the estimate or analysis, it need not prepare one under UMRA.

We reviewed the analyses to describe the extent to which they incorporated the best practices recommended by OMB's guidance. Specifically, we examined the analyses' treatment of alternatives, benefits and costs, uncertainty, and assumptions, as well as of the requirement for full disclosure. We did not, however, verify the accuracy of the data used in the analyses. Although OMB's guidance did not discuss the use of executive summaries or peer review, we also determined whether the analyses contained executive summaries or underwent peer review. We verified our findings through interviews with agency officials who were responsible for preparing the analyses.

To describe how the agencies used the economic analyses in regulatory decision-making, we interviewed agency officials with decision-making responsibility for the 20 rules to obtain more detailed explanations of how the analyses were used. Because our scope involved rules that had already progressed to the proposed or final rulemaking stages, we were unlikely to address situations in which an economic analysis resulted in a determination not to regulate or significantly alter the regulation under consideration. To account for this limitation, we asked agency officials if they were aware of other regulatory actions outside our scope in which an analysis played an important role in withdrawing or significantly altering a regulatory initiative.

We conducted this review between April 1997 and April 1998 in accordance with generally accepted government auditing standards.

Economic Analyses Incorporated Best Practices to Varying Degrees, and Some Lacked Full Disclosure

OMB's guidance sets forth best practices for federal agencies to consider in preparing economic analyses. Although incorporating these best practices can provide valuable information, the guidance recognizes that economic analyses cannot be written according to a formula. Accordingly, it gives agencies the flexibility to use their professional judgment in deciding how thorough their analyses should be. At the same time, the guidance stresses the importance of full disclosure. Therefore, in this review of the extent to which 20 economic analyses incorporated OMB's best practices, we focused not only on which best practices were included but also on whether and how clearly the agencies' methods were explained.[8]

Some of the 20 economic analyses that GAO reviewed did not incorporate the best practices set forth in OMB's guidance. For example, the 20 economic analyses varied in the number and range of alternatives considered; the degree to which benefits and costs were described—in monetary, quantitative, or qualitative terms—for the proposed action and alternatives; the degree to which assumptions and key variables were explained; and the ways in which uncertainty was accounted for in the analyses' conclusions. In some instances, the analyses provided only a limited discussion of alternatives or other best practices. Additionally, when the analyses omitted or only partially incorporated OMB's best practices, they typically did not explain the reasons for these omissions. This lack of explanation is not consistent with the principle of full disclosure. Furthermore, in some instances, the lack of full disclosure obscured the thoroughness of an agency's efforts and/or the constraints on the agency's time or resources. In these instances, full disclosure would have enhanced the reader's understanding and the credibility of the analyses.

The clarity of the 20 analyses varied, making it difficult for readers to determine whether or where OMB's best practices were considered. Some of the analyses contained executive summaries, while others relied on the preambles to the proposed and final rules, published in the Federal Register, to summarize their results. GAO has recommended, and S. 981 would require, the inclusion of an executive summary in an economic analysis to clarify an agency's approach and emphasize the key points of the analysis. Only one of the analyses underwent an independent peer

[8]As mentioned in ch. 1, OMB's guidance applies to economic analyses prepared in response to the requirements of UMRA as well as of Executive Order 12866. Because agencies rarely prepare separate analyses when UMRA is applicable (only one of the nine regulations we selected that came within the scope of UMRA had a separate analysis), our findings reflect the extent to which the nine analyses called for under UMRA satisfy the act's as well as the executive order's requirements for economic analyses.

review. GAO has recommended, and S. 981 would require, the use of peer review to help ensure both the quality and the credibility of an analysis.

Analyses Varied in Incorporating Best Practices and Did Not Always Provide Reasons for Omissions

OMB's guidance describes in detail how economic analyses should consider alternatives, benefits, costs, assumptions, uncertainty, and other factors. This guidance is consistent with standard economic principles, and incorporating its recommended practices into economic analyses could provide valuable information on the benefits and costs of regulatory alternatives. Nonetheless, the guidance also notes that the amount of analysis required depends on the "importance and complexity" of the regulatory issue, as well as on the time available for analysis. In some instances, the need to respond to an emergency or meet a statutory deadline may limit an analysis. The guidance also identifies the "nature of the statutory language and the extent of statutory discretion" as important in determining how much analysis is needed. In particular, the guidance maintains that "a less detailed or intensive analysis of the entire range of regulatory options is needed when regulatory options are limited by statute." For example, the statute directing the Food and Drug Administration (FDA) to exempt small businesses from certain food labeling requirements was so prescriptive that agency officials described the implementing regulations as little more than a photocopy of the law. Nevertheless, the guidance also states that even when such limitations apply, agencies should provide some analysis of alternatives to provide decisionmakers with information for judging the consequences of statutory constraints. Finally, the guidance recognizes that practical considerations, such as constraints on resources, may limit the scope of an analysis.

OMB's guidance allows agencies to exercise their professional judgment in deciding how thorough their analyses should be. At the same time, it stresses the importance of full disclosure in presenting the analyses. Furthermore, when agencies depart from the best practices, the guidance directs them to explain why they have chosen to do so.

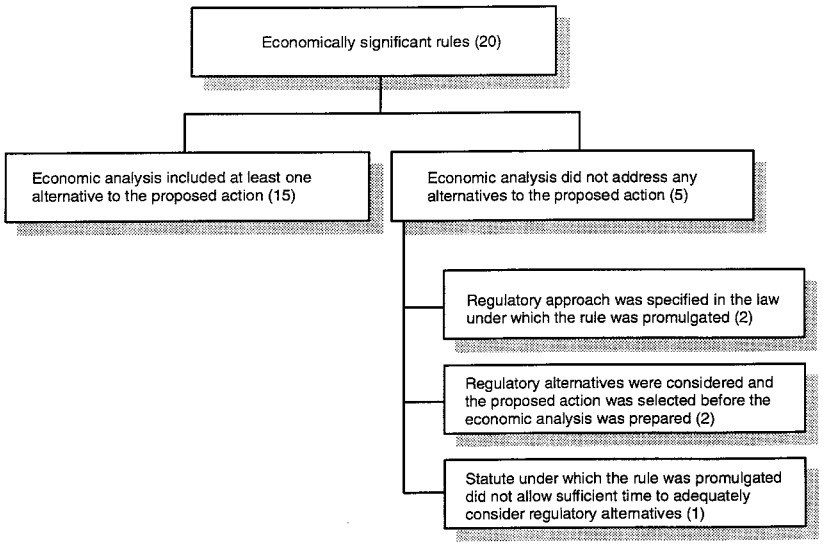
The 20 economic analyses that we reviewed varied in the extent to which they considered alternatives, described benefits and costs, explained key variables, and accounted for uncertainty. Although this variation reflects the flexibility inherent in OMB's guidance, the frequent absence of an agency's rationale for omitting or paying limited attention to certain best practices was not consistent with OMB's guidance.

Analyses Considered Alternatives to Varying Degrees

According to OMB, a key goal of an economic analysis in rulemaking is to determine what degree of regulation is needed to maximize net benefits. An economic analysis cannot determine whether net benefits are maximized unless it considers the most important regulatory alternatives or, in the words of the Executive Order, "potentially effective and reasonably feasible alternatives." Therefore, a complete analysis considers a range of alternatives, measures the benefits and costs of each, and determines which one achieves the greatest net benefits.

In 15 of the 20 analyses that we reviewed, the agencies included at least one alternative to the proposed action, but in some instances, discussion of the alternative was limited. The five other analyses did not indicate why alternatives were not discussed. Agency officials told us that, in preparing two analyses, they considered alternatives but did not discuss them in the analyses. In preparing the three remaining analyses, agency officials told us they did not consider alternatives to the proposed actions either because the authorizing statute (1) specified the regulatory approach to take or (2) did not provide enough time to consider regulatory alternatives. Figure 2.1 summarizes our findings.

Figure 2.1: Economic Analyses' Consideration of Alternatives



Agency officials provided us with reasons for not discussing or considering alternatives in the analyses. These reasons—including the specificity of, or the time constraints imposed by, the authorizing statute—are among those that OMB's guidance cites as legitimate constraints on an agency's consideration of alternatives. Although the guidance states that these can be legitimate reasons limiting the consideration of alternatives, it also states that even when such limitations apply, agencies should provide some analysis of alternatives to provide

decisionmakers with information for judging the consequences of statutory constraints. In addition, we noticed that agencies did not always document in their analyses why they did not discuss or consider alternatives in the analyses. For example, for one analysis, EPA initially considered two alternatives for implementing a regulation on certification standards for detergents added to gasoline to reduce emissions. One alternative specified the steps manufacturers should take to comply with the regulation; the other established performance-based standards and allowed the manufacturers to decide how they would achieve the standards. Because Executive Order 12866 and OMB's guidance favor performance-based regulations over command-and-control regulations, EPA dismissed the command-and-control alternative before preparing the analysis and discussed only the performance-based alternative in the analysis. FDA's regulation exempting small businesses from certain food-labeling requirements also included no alternatives and provided no explanation for this departure from OMB's guidance. FDA officials told us, however, that the legislation setting forth the exemptions was so specific that no alternative to the proposed action was feasible.

The 15 analyses that included at least one alternative also varied in the attention given to the alternative or alternatives that were considered and rejected. For example, the analysis for the regulation on adolescents' use of tobacco examined six regulatory alternatives but contained only a few paragraphs on the five that were ultimately rejected. According to the responsible officials, FDA gathered and reviewed data for all six alternatives, and experts evaluated each one before FDA proposed an action. The final economic analysis did not reflect the thoroughness of FDA's review. A more thorough discussion of the alternatives would have enabled the reader to better understand why the agency chose the proposed action.

Analyses Varied in Their Treatment of Benefits and Costs

According to OMB, an economic analysis should measure the benefits and costs of the proposed action and of the alternatives in comparable terms to ensure an accurate determination of net benefits. The benefits and costs should be measured against a baseline, preferably in numerical terms. A baseline generally describes the condition that is expected to exist without the regulation and provides a standard for measuring the incremental benefits and costs of each alternative. When possible, dollar values should be assigned to benefits and costs to enhance the consideration of regulatory alternatives that may produce equal or greater benefits at lower costs. However, if dollar values cannot be assigned, the benefits and costs

should be expressed in consistent quantitative or qualitative terms. Although completeness is desirable, OMB's guidance recognizes that accurate data may not always be available for estimating benefits and costs and that agencies may not have the resources or the time to estimate values for every alternative.

All 20 Analyses Included Baseline Information

In the 20 economic analyses that we reviewed, the baseline was either explicitly identified or was implicit within the context of the analysis. In these later analyses, the use of a baseline was more difficult to discern but was evident after some review. For example, the analysis for the U.S. Department of Agriculture's (USDA) rule on mandatory controls to reduce foodborne illness from meat and poultry did not explicitly identify a baseline. However, our review of the analysis indicated that costs were indeed measured relative to a baseline because they reflected the costs of the manufacturing controls that would be put in place after the regulation became operative.

FDA's regulation to restrict adolescents' use of tobacco describes the baseline quantitatively in terms of the number of adolescents who, in the absence of additional regulation, would be likely to start smoking each year—estimated to be 1 million under the age of 18. Although the analysis does not assign a dollar value to the costs of the baseline, it does quantify the effects of cutting the number of underage smokers in half, calculating how many fewer adults would smoke, how many deaths would be avoided, and how many life-years would be saved. The analysis then assigns dollar values to these benefits and concludes that the total monetary value of a 50-percent reduction in adolescents' use of tobacco would be between $28 billion and $43 billion at a 3-percent discount rate or between $9 billion and $10 billion at a 7-percent discount rate.

Analyses Estimated Some Benefits and Costs

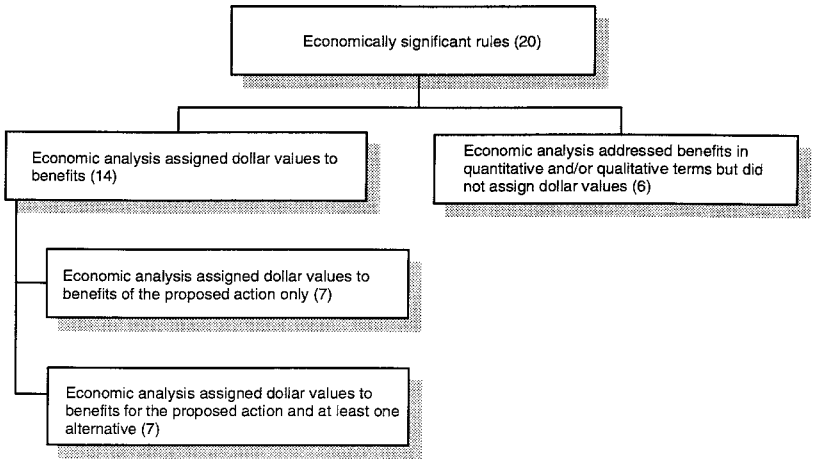
All 20 economic analyses that we reviewed estimated benefits in some terms—whether monetary, quantitative or qualitative. Fourteen[9] of the analyses assigned dollar values to some benefits. Seven of these analyses assigned dollar values to benefits for both the proposed action and at least one alternative, while the other seven assigned dollar values only for the proposed action. The analyses that did not assign dollar values to benefits did not document their reasons for omitting this element of OMB's

[9]For 1 of these 14 analyses—on lead-based paint abatement activities in certain housing and child-occupied facilities—no data were available to estimate the incremental benefits of the training required for certification and to compare these benefits with the incremental costs of the rule. Consequently, EPA decided to estimate the total benefits of lead paint abatement work and compare these benefits with the incremental costs of the rule in a break-even type of analysis, since these figures were not appropriate for a net benefit analysis.

guidance. Furthermore, only six analyses specifically identified net benefits (benefits remaining after costs have been accounted for)—a key element in OMB's guidance. Executive Order 12866 emphasizes that agencies should select approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity), unless a statute requires another regulatory approach.[10]

Figure 2.2 shows the extent to which the 20 analyses assigned dollar values to benefits.

Figure 2.2: Economic Analyses' Assignment of Dollar Values to Benefits



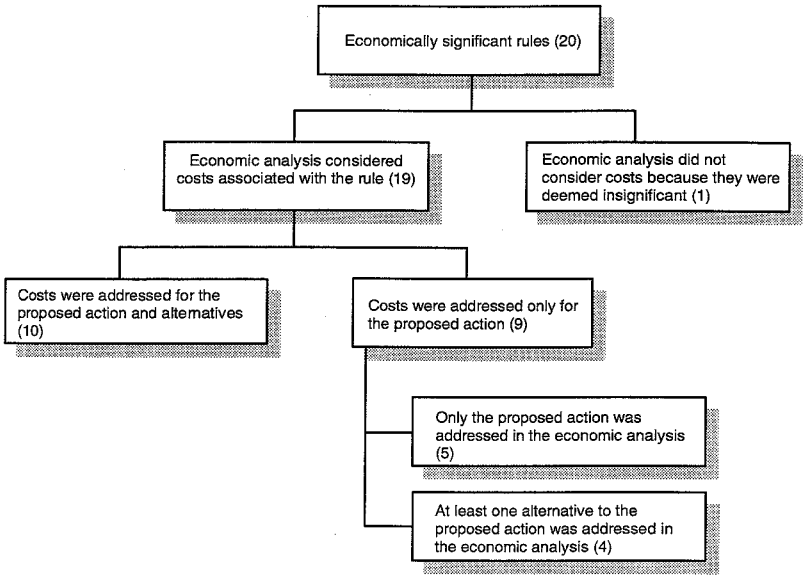
[10]Distributive impacts (or equity) indicate how the benefits and costs of a proposed regulatory action are distributed across individual members or groups or classes in society. While recognizing that distributive impacts and equity are important considerations in making decisions, economists sometimes treat them separately from net benefits.

Agencies assigned dollar values to different types of benefits, including health benefits and costs saved. For example, EPA's analyses for regulations on ozone and particulate matter assigned dollar values to health and other benefits gained through reductions in exposure to these two substances. These benefits included life-years saved and increases in crop yields. EPA's analysis for a regulation on landfills assigned dollar values to the cost savings achieved by using two new, less expensive methods of providing financial assurance. EPA estimated these savings by subtracting the costs of using the new methods from the costs of using the current method and determining the dollar savings. Finally, FDA's analysis for a regulation on ensuring disease-free animal feed assigned dollar values to the costs avoided by not having to destroy cattle.

Agencies' analyses described benefits in quantitative or qualitative terms, sometimes in combination with dollar values. For example, EPA's analysis for a rule on gas certification standards assigned dollar values to fuel consumption benefits, quantified emission reduction benefits, and qualitatively described improvements in maintenance. Four other EPA analyses—those for regulations on federal engine-testing procedures, locomotives, acid rain and nitrogen oxides, and marine engines—also quantified emission reduction benefits. The analysis for the rule on marine engine emissions qualitatively described other improvements in air quality. Other benefits that were described in quantitative or qualitative terms included reductions in fatalities due to accidents, deaths avoided through reductions in exposure to cancer-causing agents, reductions in injuries and impairments, and improvements in health.

Nineteen of the 20 analyses that we reviewed assigned dollar values to some costs. However, nine of the analyses estimated dollar values only for the proposed action. Four of these nine analyses discussed at least one other alternative but did not assign dollar values to them, while the other five did not discuss any alternatives to the proposed action. Figure 2.3 shows how the 20 analyses assigned dollar values to costs.

figure 2.3: Economic Analyses' Assignment of Dollar Values to Costs



Analyses Differed in Treatment of Assumptions and Uncertainty

To determine the present value of future benefits and costs, analysts apply a discount rate. When attempting to estimate the dollar value of benefits for regulations anticipated to extend or save lives, they may use the value of a "statistical life."[11] And to help quantify the effect of uncertainty on benefit and cost estimates, they may use sensitivity or other types of

[11]A "statistical life" is the product of (1) one minus the estimated probability of death, given no remediation of the problem that the regulation is supposed to correct, and (2) the size of the affected population.

analyses.[12] Although OMB's guidance provides agencies with flexibility in selecting assumptions and treating uncertainty, the guidance stresses that agencies should explicitly identify the assumptions underlying their economic analyses and the uncertainty associated with the resulting estimates. The economic analyses we reviewed often were not explicit on these matters.

Key Variables Differed, and Reasons for Differences Were Not Stated

Many economic analyses rely on assumed values of key variables, such as the discount rate and the value of a statistical life, to estimate the benefits and costs of regulations. In economic analyses, the discount rate is the interest rate used to determine the present value of future benefits and costs. The statistical value placed on a human life greatly affects estimates of benefits gained through improvements in safety, reductions in exposure to harmful substances, and other types of health benefits. For analyses that do not estimate values over time, a discount rate is not relevant. Similarly, for analyses that do not consider the impact of regulatory alternatives on human health or safety, the statistical value of a human life is not relevant.

Of the 20 analyses that we reviewed, 15 used one or more discount rates, which ranged from 2.1 percent to 10 percent. While OMB recommends a 7-percent discount rate (adjusted for inflation) for economic analyses, the guidance allows agencies to use different rates if justified. The majority of the 15 analyses that used a discount rate followed OMB's recommendation. The five analyses that did not use a discount rate did not explain why they did not do so. A discount rate was not used because (1) benefits and costs were estimated over only 1 year or (2) dollar values were not assigned to either benefits or costs.

For 6 of the 20 analyses, a reduction in the risk of mortality was a benefit associated with the rule, and a dollar value was, therefore, assigned to a statistical human life for the purpose of calculating benefits. The value of this statistical life varied in the six analyses, ranging from $1.6 million to $5.5 million, as indicated in table 2.1. OMB's guidance does not prescribe any particular value for agencies to use and allows for a variety of approaches to estimate the benefits of a reduction in the risk of mortality, including both explicit and implicit valuation methods. In each of the six analyses, the agency fully explained the basis for the assigned value. For the analysis for the lead paint rule, EPA estimated the mean value of a statistical life from 26 selected studies.

[12]A sensitivity analysis assigns a variety of numerical values to key parameters, such as the discount rate, to see how sensitive the benefit and cost estimates are to these different values.

Table 2.1: Dollar Value Assigned to Human Life

Dollars in millions

Analysis for rule	Assigned value
Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems	$1.6
Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents	$2.5
National Ambient Air Quality Standards for Ozone	$4.8
National Ambient Air Quality Standards for Particulate Matter	$4.8
Medical Devices: Current Good Manufacturing Practice	$5.0[a]
Lead; Requirements for Lead-Based Paint Activities in Target Housing and Child-Occupied Facilities	$5.5

[a]The economic analysis for this regulation did not assign a specific value to human life. However, the preamble to the rule published in the Federal Register estimates this value at $5.0 million.

Of the 14 analyses that did not assign a dollar value to human life, 11 did not identify a reduction in the risk of mortality as a benefit; therefore, a value for life was not applicable. The three other analyses that did have an impact on the risk of mortality were prepared by the National Highway Traffic Safety Administration and the Occupational Safety and Health Administration (OSHA). According to agency officials, the agency does not assign an explicit dollar value to human life or suffering in its analyses because it believes that such a value conveys a false sense of precision and is morally objectionable. Instead, the agencies prefer to describe benefits quantitatively in terms of fewer deaths, injuries, or illnesses.

Majority of Analyses Acknowledged Some Uncertainty

Uncertainty may arise from lack of data, variability in populations or natural conditions, limitations in fundamental scientific knowledge (both social and natural) that result in lack of knowledge about key relationships, or the fundamental unpredictability of certain phenomena. While recognizing that the effects of regulatory actions are often uncertain, OMB's guidance observes that the probability of their occurrence can, in some instances, be predicted through the use of appropriate statistical techniques. In other instances, when different assumptions are plausible, sensitivity analyses can be used to test the impact of the differences.

For 15 of the 20 regulations, the economic analyses or other related documents acknowledged the uncertainty associated with estimates of benefits and/or costs. Seven of the 15 economic analyses used sensitivity

analysis to evaluate the impact of different assumptions on the estimates, and eight of the analyses discussed uncertainties either qualitatively or in terms of ranges of estimates. The five analyses that did not discuss uncertainties did not document the agencies' reasons for not doing so.

FDA's economic analysis for the regulation to restrict adolescents' use of tobacco illustrates the role of sensitivity analysis in regulatory decision-making. For this analysis, FDA assigned dollar values to the health benefits that it estimated would result from reducing, by varying percentages, the number of adolescents who currently use tobacco, assuming a 3-percent discount rate. It estimated that a 50-percent reduction in the number of adolescent smokers would produce annual benefits of $28.1 billion to $43.2 billion, while a 5-percent reduction would produce annual benefits of $2.8 billion to $4.3 billion. Under either scenario, the estimated annual benefits would vastly outweigh the estimated annual costs of complying with the regulation—$149 million to $185 million. Although FDA did not identify a single-value "best estimate" for anticipated net benefits, it did provide a best estimate for reductions in tobacco use from a range of possibilities. Three other analyses also identified some types of best estimates from the range of estimates presented.

Analyses Did Not Provide a Rationale for Omitting Best Practices

While the 20 analyses that we reviewed generally incorporated elements of OMB's guidance to some degree, they seldom accounted for omissions, even when these omissions were consistent with the flexibility inherent in the guidance. As table 2.2 indicates, we found 36 instances in which best practices were not included in the analyses. Although agency officials told us that specific best practices were not relevant in 16 of these instances, these reasons were not provided in the economic analyses themselves. Overall, in only 1 of these 36 instances did the analysis fully disclose why the practice was omitted.

Table 2.2: Extent to Which Economic Analyses Provided Reasons for Not Incorporating Elements of OMB's Guidance

Recommended element	Did not incorporate element	Provided reason for not incorporating element
Discuss at least one alternative	5	0
Assign dollar values to some benefits	6	0
Assign dollar values to some costs	1	1
Acknowledge uncertainties	5	0
Assign a value to human life	14[a]	0
Use a discount rate	5[b]	0

[a]Element was not relevant for 11 of these analyses, and agency's policy prohibited assigning a value to human life for other 3 analyses.

[b]Element was not relevant for these analyses.

Source: GAO's analysis of 20 economic analyses.

Guidance Could Do More to Ensure Full Disclosure, and Peer Review Could Strengthen Analyses' Credibility

The clarity of the 20 analyses that we reviewed varied, making it difficult for the reader to determine whether or where particular elements of OMB's guidance were incorporated. While about half of the analyses included some form of summary, the other half used the preambles to the rules to summarize key information. Because only one of the analyses was submitted for an independent peer review, most of the analyses did not benefit from the enhanced credibility that such a review could have conferred.

Executive Summaries Frequently Not Provided

Twelve of the 20 analyses contained an executive summary that clearly and concisely summarized the reports' major findings and eight did not. In general, when agencies did not provide an executive summary, they relied on the preamble to the final or proposed rule, published in the Federal Register, to summarize the results of their work. In terms of full disclosure, the preambles were subject to the same limitations as the analyses.

As we have noted in prior reviews of EPA's economic analyses,[18] the lack of a summary in an economic analysis restricts the ability of the Congress, the public, and at times the decisionmakers to quickly identify key issues

[18]Cost-Benefit Analysis Can Be Useful in Assessing Environmental Regulations, Despite Limitations (GAO/RCED-84-62, Apr. 6, 1984) and Air Pollution: Information Contained in EPA's Regulatory Impact Analyses Can Be Made Clearer (GAO/RCED-97-38, Apr. 14, 1997).

and to be fully informed. Accordingly, we recommended to EPA that its economic analyses should, to the extent possible, include executive summaries that identify (1) all benefits and costs—even those that cannot be quantified; (2) the range of uncertainties associated with the benefits and costs; and (3) a comparison of feasible alternatives. S. 981 would require agencies to include an executive summary in the economic analyses. The summary would include, among other things, (1) the benefits and costs expected to result from the rule, (2) the benefits and costs of reasonable alternatives considered by the agency, and (3) the key assumptions and scientific or economic information on which the agency relied.

Analyses Did Not Undergo Peer Review

Only 1 of the 20 analyses that we reviewed was submitted for peer review—independent experts' critical evaluation of scientific or technical work products. While OMB does not require agencies to submit their analyses for external peer review, the Administrator of OMB's Office of Information and Regulatory Affairs testified in September 1997[14] that the administration supports peer review but recognizes that it is not cost-free, in terms of an agency's resources or time. Of the five agencies whose analyses we reviewed, only EPA has a formal peer review policy in place.

GAO is on record in support of peer review for important economic analyses. At a March 1997 hearing on peer review at EPA, we said that "given the uncertainties associated with predicting the future economic impacts of various regulatory alternatives, the rigorous, independent review of economic analyses should help enhance the products'—and the associated agency decisions'—quality, credibility, and acceptability."

EPA's peer review policy, issued in 1994, applies to major scientific or technical work products that may affect policy or regulatory decisions. Each office is to develop procedures for implementing the policy that include preparing a list of products for peer review during the upcoming year and documenting the status of products previously nominated. The policy is somewhat flexible, noting that statutory and court-ordered deadlines, resource limitations, and other constraints may limit or even preclude the use of peer review. Accordingly, the policy calls for different levels of peer review, depending upon these constraints, as well as the products'—and associated decisions'—complexity and sensitivity. Factors

[14]Statement of Sally Katzen, Administrator, Office of Information and Regulatory Affairs, OMB, before the Senate Committee on Governmental Affairs (Sept. 12, 1997).

to take into account in making decisions about peer review include whether or not the product

- establishes a significant precedent, model or methodology;
- addresses significant controversial issues;
- focuses on significant emerging issues;
- has significant cross-agency/interagency implications;
- involves a significant investment of the agency's resources;
- considers an innovative approach for a previously defined problem/process/methodology; or
- satisfies a statutory or legal mandate for peer review.

Under the policy, soliciting stakeholders' involvement or public comment is not a substitute for peer review, which is intended to solicit the independent, objective views of experts. While these experts may be internal or external to the agency, EPA's revised guidance on peer review[15] states that external peer reviewers are generally preferred. Regardless of their relationship to the agency, the reviewers should be unbiased (i.e. have not contributed to the product's development or have a material stake in the outcome of the review) and have appropriate expertise. The guidance also notes that in some circumstances, peer review may not be needed or may not be possible. For example, products that are primarily based on work that was previously peer reviewed can generally forgo additional peer review. According to the guidance, "in a few instances, statutory and court ordered deadlines and other time constraints may limit or preclude peer review." However, the guidance emphasizes that agency officials should "make every attempt possible to assure that peer review of major work products occurs taking into account these deadlines." The guidance also provides discretion in determining the timing and frequency of peer review, noting that different products warrant differing timing and frequency. A common approach is to have a single peer review when the final draft product becomes available. The guidance also states that the final product should incorporate the peer reviewers' comments or state why these comments are not incorporated.

EPA acknowledges that its implementation of the policy has been uneven, and it has taken steps to better ensure that the policy is understood, used, and considered more seriously. In response to recommendations we made in 1996, EPA has agreed to adopt steps to ensure that all major products are considered for peer review and to identify individual products that are not

[15]Science Policy Council Handbook: Peer Review (EPA 100-B-98-001, Jan. 1998).

selected for review.[15] EPA officials told us that they were considering peer reviews for some economic analyses in the future.

Officials at the agencies we visited acknowledged that peer review could improve the quality and credibility of economic analyses. For example, USDA officials told us that the results of peer reviews provide useful, ongoing guidance for economic analyses prepared for similar types of proposals. However, a number of officials incorrectly identified the process of seeking public comment through the publication of proposed or final rules in the Federal Register as a form of external peer review. Other officials maintained that submitting many of the analyses we reviewed for peer review would have delayed their publication and increased their costs but might not have added value. A common theme among the agencies was that statutory directives, time constraints, and limited resources precluded them from submitting their economic analyses to external experts for peer review. Some officials also believed that they might have difficulty finding independent reviewers with the necessary expertise.

According to a panel of leading economists, peer review should be used for economic analyses supporting regulations with a potentially large impact on the economy. The panelists recommended that the reviewers be selected on the basis of their expertise and reputation. The panel also recommended that agencies use a standard format to present their results, including a summary highlighting key results and uncertainties.[17] A recent report by the Presidential/Congressional Commission on Risk Assessment and Risk Management also supported the use of peer review for key economic documents.[18] In a recent article co-authored by EPA's Associate Assistant Administrator for Policy, Planning, and Evaluation, the authors stressed the importance of conducting economic analyses in a more open manner, involving outside experts and stakeholders. They also suggested that despite time constraints, such outside involvement could occur more often if economic analyses were initiated at the beginning of the rulemaking process.[19]

[16]Peer Review: EPA's Implementation Remains Uneven (RCED-96-236, Sept. 1996).

[17]Arrow, Cropper, et al., Benefit-Cost Analysis in Environmental, Heath, and Safety Regulation: A Statement of Principles (1996).

[18]Risk Assessment and Risk Management in Regulatory Decision-Making, The Presidential/Congressional Commission on Risk Assessment and Risk Management (1997).

[19]"Economic Analysis: Benefits, Costs, Implications," Economic Analyses at EPA: Assessing Regulatory Impact (1997).

Conclusions

Agencies' economic analyses sometimes omitted best practices recommended by OMB's guidance. While agencies have taken advantage of the flexibility that OMB's guidance gives them to use their professional judgment in deciding how thorough their analyses should be, they often have not documented the reasons why they omitted best practices recommended by the guidance—even when their reasons are among those that OMB has identified as legitimate for limiting an analysis. Full disclosure would be consistent with the guidance and would provide decisionmakers with information for judging the consequences of statutory constraints. Thus, full disclosure could generally enhance the credibility of the analyses. Similarly, including executive summaries with the analyses would help to highlight and succinctly present the key points supporting the agency's regulatory decision. Although independent reviews by internal or external experts may not be warranted for all economic analyses, such reviews could enhance both the quality and the credibility of the analyses.

Recommendations

To facilitate full disclosure and add credibility to the economic analyses required for regulatory decision-making, we recommend that the Director, Office of Management and Budget, amend the Office's guidance to include additional elements, the latter two of which are reflected in S. 981. Specifically, we recommend that the guidance be amended to provide that economic analyses should

- address all of the best practices identified in OMB's guidance or state the agency's reasons for not addressing them;
- contain an executive summary that briefly and concisely (1) identifies all benefits and costs—both those that can be described quantitatively and those that can be described qualitatively; (2) describes the range of uncertainties associated with the benefits and costs; and (3) compares the reasonable alternatives considered by the agency; and
- undergo an appropriate level of internal or external peer review by independent experts and state the agency's basis for selecting that level.

Agency Comments

We provided a draft of this report for comment to OMB and the five agencies that prepared the economic analyses we reviewed: USDA, FDA, EPA, DOT, and OSHA. We received comments from all of the agencies except OSHA, which informed us that it had no comments on the draft report. Most of the comments we received involved editorial or technical clarification issues, which we incorporated throughout the report as appropriate.

The agencies agreed with our findings and recommendations concerning the need for economic analyses to address OMB's best practices and include executive summaries. However, all of the agencies raised issues related to our recommendation on peer review. While USDA agreed with us that peer review is generally appropriate and useful, the Department maintained that using peer reviewers from within the agency is frequently more timely and cost-effective. Accordingly, USDA asked us to clarify what constitutes "an appropriate level of peer review." Similar requests for clarification were raised by OMB and DOT. FDA urged us to delete this recommendation altogether, maintaining that a requirement for peer review by experts external to the agency would have minimal benefits and the resource burden would likely preclude the agency from meeting its statutory requirements.

We acknowledge that peer review imposes some time and resource burdens on agencies and that different types of economic analyses warrant different levels of peer review. We believe that EPA's peer review policy addresses this issue well, providing for either internal or external peer review. However, the policy also emphasizes that, as a general rule, the more important, novel, or sensitive the document and the associated regulatory action, the more rigorous the peer review should be. The policy also emphasizes that whether the review is conducted within or outside the agency, two basic requirements must be met: The reviewers must be unbiased, and they must have appropriate expertise. We have clarified the report's discussion and recommendation on peer review to clarify that agencies should be allowed discretion in the level of peer review selected for individual analyses but should also state the basis for selecting that level.

Agencies Often Used Economic Analyses to Identify Cost-Effective Approaches

According to OMB's guidance, economic analyses should play an important role in agencies' regulatory decision-making. Agency officials said that they generally used the analyses in their decision-making, most frequently to help identify the most cost-effective alternative that would fulfill an authorizing statute's mandate. Because our scope involved rules that had already progressed to the proposed or final rulemaking stages, it was unlikely that any of the 20 analyses we reviewed resulted in the reversal of an agency's decision to regulate or led to major revisions to the proposed action. Nonetheless, agency officials told us analyses conducted early in the rulemaking stages sometimes lead to significant changes in agencies' decisions. Agency officials responsible for making regulatory decisions stated that their decisions to regulate frequently respond to specific statutory mandates or perceived emergencies.

OMB's Guidance Urges Agencies to Use Economic Analyses in Decision-Making

OMB's guidance encourages the use of economic analyses in developing regulations, stressing that "good data and good analysis are critical to inform sound decision-making." However, the guidance recognizes that the same factors that may limit the thoroughness of the analyses may also restrict their use. For example, the need to respond to an emergency, meet a statutory deadline, or comply with specific language in an authorizing statute may limit the use of an analysis. According to the guidance, the most critical of these factors is the extent to which the statute affords discretion in selecting regulatory alternatives. But even when the statute limits an agency's discretion, OMB's guidance urges the agency to "provide some analysis of other regulatory options . . . in order to provide decisionmakers with information for judging the consequences of the statutory constraints."

Most Analyses Were Used to Identify the Most Cost-Effective Approach

According to agency officials, nearly all of the economic analyses we reviewed played some role in regulatory decision-making. However, this role was most often limited to identifying and selecting the most cost-effective approach within a predetermined regulatory approach. The analyses rarely led decisionmakers to select a significantly different alternative or fundamentally revise the regulatory proposal under consideration. Table 3.1 summarizes agency officials' views on the primary uses of the 20 economic analyses.

Table 3.1: Officials' Views on How Economic Analyses Were Used in Regulatory Decision-Making

Use of analysis	Number of analyses
Identify the most cost-effective approach	10
Implement health-based regulations cost-effectively	2
Define regulation's coverage	3
Define regulation's implementation date	1
Defend/document a regulatory decision	2
Reduce health risks at feasible cost	1
Play no role in the regulatory decision	1

Note: Because some of the analyses fall into more than one category, we categorized them according to their primary use, as defined by agency officials.

Source: GAO's analysis.

The following examples show how agencies have used economic analyses in their regulatory decision-making:

- Identify the most cost-effective approach: The economic analysis for EPA's proposed rule on emission standards for marine engines estimated manufacturers' compliance costs for different emission standards. According to EPA officials who prepared the analyses and were involved in the decision-making process, the analysis clearly identified the point at which greater reductions in emissions would come at a dramatically higher cost to industry. The EPA decisionmaker for this rule recalled asking her staff why EPA could not set the standards more stringently and being told that the analysis had demonstrated that the proposed standard was the most cost-effective of several alternatives considered.
- Implement health-based regulations cost-effectively: In some instances, according to EPA and the courts, regulatory decisions are to be based on health rather than cost or other considerations. In setting primary air quality standards for ozone and particulate matter, EPA maintained that its first responsibility under the law was "to select standards that protect public health" with "an adequate margin of safety." According to EPA's and the courts' interpretation of the Clean Air Act, the setting of these standards is a health-based decision that specifically is not to be based on cost or other economic considerations. Nevertheless, the agency maintains that economic analyses could help inform decisionmakers on ways to implement these health-based standards cost-effectively. In addition, according to EPA, the analyses can inform the public about the potential costs and benefits of implementing the regulations.
- Define a regulation's coverage: The Federal Agriculture Improvement and Reform Act of 1996 authorized the Secretary of Agriculture to combine

into one program the functions of several conservation programs that the act rescinded. According to USDA officials involved in the decision-making process, the economic analysis prepared for the implementing rule played "a tremendous role" in defining the "livestock operations" that are covered by the rule. Because the definition of the rule's coverage was politically contentious, the analysis also provided the agency with a basis for defending its decision.

- Reduce health risks at feasible cost: According to the preamble to OSHA's rule on methylene chloride, the agency determined, on the basis of new animal and human data, that current standards place employees at "a significant risk of material impairment of health." The preamble also states that OSHA's standards must be "highly protective" as long as they are technologically and economically feasible. The preamble then concludes, on the basis of OSHA's economic analyses, that "the rule is the most cost-effective alternative for implementation of OSHA's statutory objective of reducing significant risk to the extent feasible."
- Define a regulation's implementation date: EPA's economic analysis for a proposed rule on procedures for testing emissions from motor vehicles incorporated data provided by the automobile industry and led to revisions that gave the industry additional time to implement the final rule. After EPA published an initial cost analysis as part of a proposed rule, the industry questioned the validity of EPA's data and provided more current data. EPA then adjusted its cost calculations, dropped one component of its proposal, and extended the deadline for implementing the final rule.
- Defend a regulatory decision: According to FDA officials, the economic analysis for a rule on manufacturing medical devices provided the agency with a credible rebuttal to manufacturers' complaints that compliance costs would be excessive. USDA officials also told us that they sometimes use their analyses to defend controversial regulatory decisions.
- Play no role in the decision-making process: The economic analysis supporting FDA's final rule exempting small businesses from food-labeling requirements played virtually no role in the decision-making process. Because the authorizing legislation—the 1993 amendments to the Federal Food, Drug, and Cosmetic Act—was so specific about who would be eligible for the exemption, the analysis was not really necessary, FDA officials said.

Statutes Limited the Use of Economic Analyses

According to agency officials, economic analyses are generally used for the purposes summarized in table 3.1 and are less frequently used for deciding whether or not to regulate or for identifying significantly different regulatory approaches. Agency officials told us that statutory mandates

frequently limited their discretion in deciding whether to regulate and/or in selecting alternative regulatory approaches. In one instance, the statute was so specific that officials described the rule as not much more than a photocopy of the law. In addition, officials cited instances in which the agency believed that it had little discretion or time to react to an emergency situation. The following are some of the other instances cited by agency officials in which the agency issued regulations in response to statutory directives or emergencies:

- In the Clean Air Act Amendments of 1990, the Congress directed EPA, within 18 months, to review and revise as necessary its regulations on testing motor vehicles and engines to ensure that the tests reflect actual, current driving conditions, including conditions related to fuel, temperature, acceleration, and altitude. Because the agency concluded that the current test procedures had shortcomings in representing, among other things, aggressive driving, rapid speed fluctuations, and the use of air conditioning, EPA decided new regulations were warranted.
- The National Highway Traffic Safety Administration Authorization Act of 1991, among other things, directed the Secretary of Transportation to determine whether additional regulations were needed to ensure the safety of child seats used in motor vehicles. In studying this issue, DOT concluded that because so many different types of seat belts were in use, the child restraints were difficult to attach correctly to improve safety. Accordingly, the Department proposed a regulation requiring the use of a specific attachment system. The proposed rule noted that there were data gaps in the economic analyses and stated that if new information became available, DOT would consider other possible alternatives.
- USDA issued emergency quarantine regulations after the Karnal Bunt disease was detected in Arizona and California. The regulations were issued about 6 months before the economic analysis was completed and published. Karnal Bunt is a serious fungal disease that can affect both the yield and quality of wheat. Although it does not present a risk to human or animal health, it makes wheat taste like fish and can dramatically affect wheat sales at home and abroad. Many countries prohibit the import of wheat from countries where Karnal Bunt is known to exist. Although the economic analysis played no role in the initial quarantine, USDA officials told us that it was useful in later decisions about the number and location of acres subject to the quarantine.

Appendix I

Major Contributors to This Report

Resources, Community, and Economic Development Division	Luther L. Atkins, Assistant Director Greg A. Kosarin, Evaluator-in-Charge Jay R. Cherlow, Assistant Director for Economic Analysis Timothy J. Guinane, Senior Economist Stephen M. Brown, Senior Economist
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II

106TH CONGRESS
1ST SESSION

S. 746

To provide for analysis of major rules, to promote the public's right to know the costs and benefits of major rules, and to increase the accountability and quality of Government.

IN THE SENATE OF THE UNITED STATES

MARCH 25, 1999

Mr. LEVIN (for himself, Mr. THOMPSON, Mr. VOINOVICH, Mr. ROBB, Mr. ABRAHAM, Mr. ROCKEFELLER, Mr. ROTH, Mr. DASCHLE, Mr. STEVENS, Mr. MOYNIHAN, Mr. COCHRAN, Mr. BREAUX, Mr. FRIST, Mr. ENZI, Mr. GRAMS, Mr. GRASSLEY, and Mrs. LINCOLN) introduced the following bill; which was read twice and referred to the Committee on Governmental Affairs

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A BILL

To provide for analysis of major rules, to promote the public's right to know the costs and benefits of major rules, and to increase the accountability and quality of Government.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Regulatory Improvement Act of 1999".

SEC. 2. FINDINGS.

Congress finds the following:

(1) Effective regulatory programs provide important benefits to the public, including improving the environment, worker safety, and public health. Regulatory programs also impose significant costs on the public, including individuals, businesses, and State, local, and tribal governments.

(2) Improving the ability of Federal agencies to use scientific and economic analysis in developing regulations should yield increased benefits and more effective protections while minimizing costs.

(3) Cost-benefit analysis and risk assessment are useful tools to better inform agencies in developing regulations, although such analyses and assessments do not replace the need for good judgment and consideration of values.

(4) The evaluation of costs and benefits must involve the consideration of the relevant information, whether expressed in quantitative or qualitative terms, including factors such as social values, distributional effects, and equity.

(5) Cost-benefit analysis and risk assessment should be presented with a clear statement of the analytical assumptions and uncertainties, including an explanation of what is known and not known and

what the implications of alternative assumptions might be.

(6) The public has a right to know about the costs and benefits of regulations, the risks addressed, the risks reduced, and the quality of scientific and economic analysis used to support decisions. Such knowledge will promote the quality, integrity and responsiveness of agency actions.

(7) The Administrator of the Office of Information and Regulatory Affairs should oversee regulatory activities to raise the quality and consistency of cost-benefit analysis and risk assessment among all agencies.

(8) The Federal Government should develop a better understanding of the strengths, weaknesses, and uncertainties of cost-benefit analysis and risk assessment and conduct the research needed to improve these analytical tools.

SEC. 3. REGULATORY ANALYSIS.

(a) IN GENERAL.—Chapter 6 of title 5, United States Code, is amended by adding at the end the following:

"SUBCHAPTER II—REGULATORY ANALYSIS

"§ 621. Definitions

"For purposes of this subchapter the definitions under section 551 shall apply and—

"(1) the term 'Administrator' means the Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget;

"(2) the term 'benefit' means the reasonably identifiable significant favorable effects, quantifiable and nonquantifiable, including social, health, safety, environmental, economic, and distributional effects, that are expected to result from implementation of, or compliance with, a rule;

"(3) the term 'cost' means the reasonably identifiable significant adverse effects, quantifiable and nonquantifiable, including social, health, safety, environmental, economic, and distributional effects, that are expected to result from implementation of, or compliance with, a rule;

"(4) the term 'cost-benefit analysis' means an evaluation of the costs and benefits of a rule, quantified to the extent feasible and appropriate and otherwise qualitatively described, that is prepared in accordance with the requirements of this subchapter at

the level of detail appropriate and practicable for reasoned decisionmaking on the matter involved, taking into consideration uncertainties, the significance and complexity of the decision, and the need to adequately inform the public;

"(5) the term 'Director' means the Director of the Office of Management and Budget, acting through the Administrator of the Office of Information and Regulatory Affairs;

"(6) the term 'flexible regulatory options' means regulatory options that permit flexibility to regulated persons in achieving the objective of the statute as addressed by the rule making, including regulatory options that use market-based mechanisms, outcome oriented performance-based standards, or other options that promote flexibility;

"(7) the term 'major rule' means a rule that—

"(A) the agency proposing the rule or the Director reasonably determines is likely to have an annual effect on the economy of $100,000,000 or more in reasonably quantifiable costs; or

"(B) is otherwise designated a major rule by the Director on the ground that the rule is likely to adversely affect, in a material way, the

economy, a sector of the economy, including small business, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments, or communities;

"(8) the term 'reasonable alternative' means a reasonable regulatory option that would achieve the objective of the statute as addressed by the rule making and that the agency has authority to adopt under the statute granting rule making authority, including flexible regulatory options;

"(9) the term 'risk assessment' means the systematic, objective process of organizing hazard and exposure information, based on a careful analysis of the weight of the scientific evidence, to estimate the potential for specific harm to an exposed population, subpopulation, or natural resource including, to the extent feasible, a characterization of the distribution of risk as well as an analysis of uncertainties, variabilities, conflicting information, and inferences and assumptions;

"(10) the term 'rule' has the same meaning as in section 551(4), and shall not include—

"(A) a rule exempt from notice and public comment procedure under section 553;

"(B) a rule that involves the internal revenue laws of the United States, or the assessment or collection of taxes, duties, or other debts, revenue, or receipts;

"(C) a rule of particular applicability that approves or prescribes for the future rates, wages, prices, services, corporate or financial structures, reorganizations, mergers, acquisitions, accounting practices, or disclosures bearing on any of the foregoing;

"(D) a rule relating to monetary policy proposed or promulgated by the Board of Governors of the Federal Reserve System or by the Federal Open Market Committee;

"(E) a rule relating to the operations, safety, or soundness of federally insured depository institutions or any affiliate of such an institution (as defined in section 2(k) of the Bank Holding Company Act of 1956 (12 U.S.C. 1841(k)); credit unions; the Federal Home Loan Banks; government-sponsored housing enterprises; a Farm Credit System Institution; foreign banks, and their branches, agencies, commercial lending companies or representative offices that operate in the United States and

any affiliate of such foreign banks (as those terms are defined in the International Banking Act of 1978 (12 U.S.C. 3101)); or a rule relating to the payments system or the protection of deposit insurance funds or Farm Credit Insurance Fund;

"(F) a rule relating to the integrity of the securities or commodities futures markets or to the protection of investors in those markets;

"(G) a rule issued by the Federal Election Commission or a rule issued by the Federal Communications Commission under sections 312(a)(7) and 315 of the Communications Act of 1934 (47 U.S.C. 312(a)(7) and 315);

"(H) a rule required to be promulgated at least annually pursuant to statute;

"(I) a rule or agency action relating to the public debt or fiscal policy of the United States; or

"(J) a rule or agency action that authorizes or bars the introduction into or removal from commerce, or recognizes or cancels recognition of the marketable status, of a product under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq.); and

"(11) the term 'substitution risk'—

"(A) means a reasonably identifiable significant increased risk to health, safety, or the environment expected to result from a regulatory option; and

"(B) shall not include risks attributable to the effect of an option on the income of individuals.

"§ 622. Applicability and effect

"(a) Except as provided in section 623(f), this subchapter shall apply to all proposed and final major rules.

"(b) Nothing in this subchapter shall be construed to alter or modify—

"(1) the substantive standards applicable to a rule making under other statutes;

"(2)(A) the range of regulatory options that an agency has the authority to adopt under the statute authorizing the agency to promulgate the rule; or

"(B) the deference otherwise accorded to the agency in construing such statute; or

"(3) any opportunity for judicial review made applicable under other statutes.

"§ 623. Regulatory analysis

"(a)(1) Before publishing a notice of a proposed rule making for any rule, each agency shall determine whether

the rule is or is not a major rule covered by this subchapter.

"(2) The Director may designate any rule to be a major rule under section 621(7)(B), if the Director—

"(A) makes such designation not later than 30 days after the close of the comment period for the rule; and

"(B) publishes such designation in the Federal Register, together with a succinct statement of the basis for the designation, within 30 days after such designation.

"(b)(1)(A) When an agency publishes a notice of proposed rule making for a major rule, the agency shall—

"(i) prepare and place in the rule making file an initial regulatory analysis; and

"(ii) include a summary of such analysis consistent with subsection (e) in the notice of proposed rule making.

"(B)(i) When the Director has published a designation that a rule is a major rule after the publication of the notice of proposed rule making for the rule, the agency shall—

"(I) promptly prepare and place in the rule making file an initial regulatory analysis for the rule; and

"(II) publish in the Federal Register a summary of such analysis consistent with subsection (e).

"(ii) Following the issuance of an initial regulatory analysis under clause (i), the agency shall give interested persons an opportunity to comment under section 553 in the same manner as if the initial regulatory analysis had been issued with the notice of proposed rule making.

"(2) Each initial regulatory analysis shall contain—

"(A) a cost-benefit analysis of the proposed rule that shall contain—

"(i) an analysis of the benefits of the proposed rule, including any benefits that cannot be quantified, and an explanation of how the agency anticipates that such benefits will be achieved by the proposed rule, including a description of the persons or classes of persons likely to receive such benefits;

"(ii) an analysis of the costs of the proposed rule, including any costs that cannot be quantified, and an explanation of how the agency anticipates that such costs will result from the proposed rule, including a description of the persons or classes of persons likely to bear such costs;

"(iii) an evaluation of the relationship of the benefits of the proposed rule to its costs, including the determinations required under subsection (d), taking into account the results of any risk assessment;

"(iv) an evaluation of the benefits and costs of a reasonable number of reasonable alternatives reflecting the range of regulatory options that would achieve the objective of the statute as addressed by the rule making, including, where feasible, alternatives that—

"(I) require no government action or utilize voluntary programs;

"(II) provide flexibility for small entities under subchapter I and for State, local, or tribal government agencies delegated to administer a Federal program;

"(III) employ flexible regulatory options; and

"(IV) assure protection of sensitive subpopulations, or populations exposed to multiple and cumulative risks; and

"(v) a description of the scientific or economic evaluations or information upon which the agency substantially relied in the cost-ben-

efit analysis and risk assessment required under this subchapter, and an explanation of how the agency reached the determinations under subsection (d);

"(B) if required, the risk assessment in accordance with section 624; and

"(C) when scientific information on substitution risks to health, safety, or the environment is reasonably available to the agency, an identification and evaluation of such risks.

"(c)(1) When the agency publishes a final major rule, the agency shall prepare and place in the rule making file a final regulatory analysis.

"(2) Each final regulatory analysis shall address each of the requirements for the initial regulatory analysis under subsection (b)(2), revised to reflect—

"(A) any material changes made to the proposed rule by the agency after publication of the notice of proposed rule making;

"(B) any material changes made to the cost-benefit analysis or risk assessment; and

"(C) agency consideration of significant comments received regarding the proposed rule and the initial regulatory analysis, including regulatory review communications under subchapter IV.

"(d)(1)(A) The agency shall include in the statement of basis and purpose for a proposed or final major rule a reasonable determination, based upon the rule making record considered as a whole—

"(i) whether the rule is likely to provide benefits that justify the costs of the rule;

"(ii) whether the rule is likely to substantially achieve the rule making objective in a more cost-effective manner, or with greater net benefits, than the other reasonable alternatives considered by the agency; and

"(iii) whether the rule adopts a flexible regulatory option.

"(B) Consistent with section 621 (2) and (3), net benefits analysis shall not be construed to be limited to quantifiable effects.

"(2) If the agency head determines that the rule is not likely to provide benefits that justify the costs of the rule or is not likely to substantially achieve the rule making objective in a more cost-effective manner, or with greater net benefits, than the other reasonable alternatives considered by the agency, the agency head shall—

"(A) explain the reasons for selecting the rule notwithstanding such determination, including iden-

tifying any statutory provision that required the agency to select such rule;

"(B) describe any reasonable alternative considered by the agency that would be likely to provide benefits that justify the costs of the rule and be likely to substantially achieve the rule making objective in a more cost-effective manner, or with greater net benefits, than the alternative selected by the agency; and

"(C) describe any flexible regulatory option considered by the agency and explain why that option was not adopted by the agency if that option was not adopted.

"(e) Each agency shall include an executive summary of the regulatory analysis, including any risk assessment, in the regulatory analysis and in the statement of basis and purpose for the proposed and final major rule. Such executive summary shall include a succinct presentation of—

"(1) the benefits and costs expected to result from the rule and any determinations required under subsection (d);

"(2) if applicable, the risk addressed by the rule and the results of any risk assessment;

"(3) the benefits and costs of reasonable alternatives considered by the agency; and

"(4) the key assumptions and scientific or economic information upon which the agency relied.

"(f)(1) A major rule may be adopted without prior compliance with this subchapter if—

"(A) the agency for good cause finds that conducting the regulatory analysis under this subchapter before the rule becomes effective is impracticable or contrary to an important public interest; and

"(B) the agency publishes the rule in the Federal Register with such finding and a succinct explanation of the reasons for the finding.

"(2) If a major rule is adopted under paragraph (1), the agency shall comply with this subchapter as promptly as possible unless the Director determines that compliance would be clearly unreasonable.

"(g) Each agency shall develop an effective process to permit elected officers of State, local, and tribal governments (or their designated employees with authority to act on their behalf) to provide meaningful and timely input in the development of regulatory proposals that contain significant Federal intergovernmental mandates. The process developed under this subsection shall be consistent

with section 204 of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1534).

"§ 624. Principles for risk assessments

"(a)(1)(A) Subject to paragraph (2), each agency shall design and conduct risk assessments in accordance with this subchapter for—

"(i) each proposed and final major rule the primary purpose of which is to address health, safety, or environmental risk; or

"(ii) any risk assessment that is not the basis of a rule making that the Director—

"(I) reasonably anticipates is likely to have an annual effect on the economy of $100,000,000 or more in reasonably quantifiable costs; and

"(II) determines shall be subject to the requirements of this section.

"(B)(i) Risk assessments conducted under this subchapter shall be conducted in a manner that promotes rational and informed risk management decisions and informed public input into and understanding of the process of making agency decisions.

"(ii) The scope and level of analysis of such a risk assessment shall be commensurate with the significance and complexity of the decision and the need to adequately

inform the public, consistent with any need for expedition, and designed for the nature of the risk being assessed.

"(2) If a risk assessment under this subchapter is otherwise required by this section, but the agency determines that—

"(A) a final rule subject to this subchapter is substantially similar to the proposed rule with respect to the risk being addressed;

"(B) a risk assessment for the proposed rule has been carried out in a manner consistent with this subchapter; and

"(C) a new risk assessment for the final rule is not required in order to respond to comments received during the period for comment on the proposed rule,

the agency may publish such determination along with the final rule in lieu of preparing a new risk assessment for the final rule.

"(b) Each agency shall consider in each risk assessment all relevant, reliable, and reasonably available scientific information and shall describe the basis for selecting such scientific information.

"(c)(1) When a risk assessment involves a choice of assumptions, the agency shall, with respect to significant assumptions—

"(A) identify the assumption and its scientific and policy basis, including the extent to which the assumption has been validated by, or conflicts with, empirical data;

"(B) explain the basis for any choices among assumptions and, where applicable, the basis for combining multiple assumptions; and

"(C) describe reasonable alternative assumptions that—

"(i) would have had a significant effect on the results of the risk assessment; and

"(ii) were considered but not selected by the agency for use in the risk assessment.

"(2) Significant assumptions used in a risk assessment shall incorporate all reasonably available, relevant, and reliable scientific information.

"(d) The agency shall inform the public when the agency is conducting a risk assessment subject to this section and, to the extent practicable, shall solicit relevant and reliable data from the public. The agency shall consider such data in conducting the risk assessment.

"(e) Each risk assessment under this subchapter shall include, as appropriate, each of the following:

"(1) A description of the hazard of concern.

"(2) A description of the populations or natural resources that are the subject of the risk assessment.

"(3) An explanation of the exposure scenarios used in the risk assessment, including an estimate of the corresponding population or natural resource at risk and the likelihood of such exposure scenarios.

"(4) A description of the nature and severity of the harm that could reasonably occur as a result of exposure to the hazard.

"(5) A description of the major uncertainties in each component of the risk assessment and their influence on the results of the assessment.

"(f) To the extent scientifically appropriate, each agency shall—

"(1) express the estimate of risk as 1 or more reasonable ranges and, if feasible, probability distributions that reflects variabilities, uncertainties, and lack of data in the analysis;

"(2) provide the ranges and distributions of risks, including central and high end estimates of the risks, and their corresponding exposure scenarios for the potentially exposed population and, as appropriate, for more highly exposed or sensitive subpopulations; and

"(3) describe the qualitative factors influencing the ranges, distributions, and likelihood of possible risks.

"(g) When scientific information that permits relevant comparisons of risk is reasonably available, each agency shall use the information to place the nature and magnitude of a risk to health, safety, or the environment being analyzed in relationship to other reasonably comparable risks familiar to and routinely encountered by the general public. Such comparisons should consider relevant distinctions among risks, such as the voluntary or involuntary nature of risks, well understood or newly discovered risks, and reversible or irreversible risks.

"§ 625. Peer review

"(a) Each agency shall provide for an independent peer review in accordance with this section of—

"(1) a cost-benefit analysis of a major rule that the agency or Director reasonably anticipates is likely to have an annual effect on the economy of $500,000,000 in reasonably quantifiable costs; and

"(2) a risk assessment required by this subchapter.

"(b)(1) Peer review required under subsection (a) shall—

"(A) be conducted through panels, expert bodies, or other formal or informal devices that are broadly representative and involve participants—

"(i) with expertise relevant to the sciences, or analyses involved in the regulatory decisions; and

"(ii) who are independent of the agency;

"(B) be governed by agency standards and practices governing conflicts of interest of non-governmental agency advisors;

"(C) provide for the timely completion of the peer review including meeting agency deadlines;

"(D) contain a balanced presentation of all considerations, including minority reports and an agency response to all significant peer review comments; and

"(E) provide adequate protections for confidential business information and trade secrets, including requiring panel members or participants to enter into confidentiality agreements.

"(2) Each agency shall provide a written response to all significant peer review comments. All peer review comments and any responses shall be made—

"(A) available to the public; and

"(B) part of the rule making record for purposes of judicial review of any final agency action.

"(3) If the head of an agency, with the concurrence of the Director, publishes a determination in the rule making file that a cost-benefit analysis or risk assessment, or any component thereof, has been previously subjected to adequate peer review, no further peer review shall be required under this section for such analysis, assessment, or component.

"(c) For each peer review conducted by an agency under this section, the agency head shall include in the rule making record a statement by a Federal officer or employee who is not an employee of the agency rule making office or program—

"(1) whether the peer review participants reflect the independence and expertise required under subsection (b)(1)(A); and

"(2) whether the agency has adequately responded to the peer review comments as required under subsection (b)(2).

"(d) The formality of the peer review conducted under this section shall be commensurate with the significance and complexity of the subject matter.

"(e) The peer review required by this section shall not be subject to the Federal Advisory Committee Act (5 U.S.C. App.).

"(f) A member of an agency advisory board (or comparable organization) established by statute shall be considered independent of the agency for purposes of subsection (b)(1)(A)(ii).

"(g) The status of a person as a contractor or grantee of the agency conducting the peer review shall not, in and of itself, exclude such person from serving as a peer reviewer for such agency because of the requirement of subsection (b)(1)(A)(ii).

"(h) Nothing in this section shall require more than one peer review of a cost-benefit analysis or a risk assessment during a rule making. A peer review required by this section shall occur to the extent feasible before the notice of proposed rule making.

"§ 626. Deadlines for rule making

"(a) All statutory deadlines that require an agency to propose or promulgate any major rule during the 2-year period beginning on the effective date of this section shall be suspended until the earlier of—

"(1) the date on which the requirements of this subchapter are satisfied; or

"(2) the date occurring 180 days after the date of the applicable deadline.

"(b) In any proceeding involving a deadline imposed by a court of the United States that requires an agency to propose or promulgate any major rule during the 2-year period beginning on the effective date of this section, the United States shall request, and the court may grant, an extension of such deadline until the earlier of—

"(1) the date on which the requirements of this subchapter are satisfied; or

"(2) the date occurring 180 days after the date of the applicable deadline.

"(c) In any case in which the failure to promulgate a major rule by a deadline occurring during the 2-year period beginning on the effective date of this section would create an obligation to regulate through individual adjudications, the deadline shall be suspended until the earlier of—

"(1) the date on which the requirements of this subchapter are satisfied; or

"(2) the date occurring 180 days after the date of the applicable deadline.

"§ 627. Judicial review

"(a) Compliance by an agency with the provisions of this subchapter shall be subject to judicial review only—

"(1) in connection with review of final agency action;

"(2) in accordance with this section; and

"(3) in accordance with the limitations on timing, venue, and scope of review imposed by the statute authorizing judicial review.

"(b) Any determination of an agency whether a rule is a major rule under section 621(7)(A) shall be set aside by a reviewing court only upon a showing that the determination is arbitrary or capricious.

"(c) Any designation by the Director that a rule is a major rule under section 621(7), or any failure to make such designation, shall not be subject to judicial review.

"(d) The cost-benefit analysis, cost-benefit determination under section 623(d), and any risk assessment required under this subchapter shall not be subject to judicial review separate from review of the final rule to which such analysis or assessment applies. The cost-benefit analysis, cost-benefit determination under section 623(d), and any risk assessment shall be part of the rule making record and shall be considered by a court to the extent relevant, only in determining under the statute granting the rule making authority whether the final rule is arbitrary, capricious, an abuse of discretion, or is unsupported

by substantial evidence where that standard is otherwise provided by law.

"(e) If an agency fails to perform the cost-benefit analysis, cost-benefit determination, or risk assessment, or to provide for peer review, a court may, giving due regard to prejudicial error, remand or invalidate the rule. The adequacy of compliance with the specific requirements of this subchapter shall not otherwise be grounds for remanding or invalidating a rule under this subchapter. If the court allows the rule to take effect, the court shall order the agency to promptly perform such analysis, determination, or assessment or provide for such peer review.

"§ 628. Guidelines, interagency coordination, and research

"(a)(1) Not later than 270 days after the date of enactment of this section, the Director, in consultation with the Council of Economic Advisors, the Director of the Office of Science and Technology Policy, and relevant agency heads, shall issue guidelines for cost-benefit analyses, risk assessments, and peer reviews as required by this subchapter. The Director shall oversee and periodically revise such guidelines as appropriate.

"(2) As soon as practicable and not later than 18 months after issuance of the guidelines required under paragraph (1), each agency subject to section 624 shall

adopt detailed guidelines for risk assessments as required by this subchapter. Such guidelines shall be consistent with the guidelines issued under paragraph (1). Each agency shall periodically revise such agency guidelines as appropriate.

"(3) The guidelines under this subsection shall be developed following notice and public comment. The development and issuance of the guidelines shall not be subject to judicial review, except in accordance with section 706(1).

"(b) To promote the use of cost-benefit analysis and risk assessment in a consistent manner and to identify agency research and training needs, the Director, in consultation with the Council of Economic Advisors and the Director of the Office of Science and Technology Policy, shall—

"(1) oversee periodic evaluations of Federal agency cost-benefit analysis and risk assessment;

"(2) provide advice and recommendations to the President and Congress to improve agency use of cost-benefit analysis and risk assessment;

"(3) utilize appropriate interagency mechanisms to improve the consistency and quality of cost-benefit analysis and risk assessment among Federal agencies; and

"(4) utilize appropriate mechanisms between Federal and State agencies to improve cooperation in the development and application of cost-benefit analysis and risk assessment.

"(c)(1) The Director, in consultation with the head of each agency, the Council of Economic Advisors, and the Director of the Office of Science and Technology Policy, shall periodically evaluate and develop a strategy to meet agency needs for research and training in cost-benefit analysis and risk assessment, including research on modelling, the development of generic data, use of assumptions and the identification and quantification of uncertainty and variability.

"(2)(A) Not later than 180 days after the date of enactment of this section, the Director, in consultation with the Director of the Office of Science and Technology Policy, shall enter a contract with an accredited scientific institution to conduct research to—

"(i) develop a common basis to assist risk communication related to both carcinogens and non-carcinogens; and

"(ii) develop methods to appropriately incorporate risk assessments into related cost-benefit analyses.

"(B) Not later than 2 years after the date of enactment of this section, the results of the research conducted under this paragraph shall be submitted to the Director and Congress.

"§ 629. Risk based priorities study

"(a) Not later than 1 year after the date of enactment of this section, the Director, in consultation with the Director of the Office of Science and Technology Policy, shall enter into a contract with an accredited scientific institution to conduct a study that provides—

"(1) a systematic comparison of the extent and severity of significant risks to human health, safety, or the environment (hereafter referred to as a comparative risk analysis);

"(2) a study of methodologies for using comparative risk analysis to compare dissimilar risks to human health, safety, or the environment, including development of a common basis to assist comparative risk analysis related to both carcinogens and noncarcinogens; and

"(3) recommendations on the use of comparative risk analysis in setting priorities for the reduction of risks to human health, safety, or the environment.

"(b) The Director shall ensure that the study required under subsection (a) is—

"(1) conducted through an open process providing peer review consistent with section 625 and opportunities for public comment and participation; and

"(2) not later than 3 years after the date of enactment of this section, completed and submitted to Congress and the President.

"(c) Not later than 4 years after the date of enactment of this section, each relevant agency shall, as appropriate, use the results of the study required under subsection (a) to inform the agency in the preparation of the agency's annual budget and strategic plan and performance plan under section 306 of this title and sections 1115, 1116, 1117, 1118, and 1119 of title 31.

"(d) Not later than 5 years after the date of enactment of this section, and periodically thereafter, the President shall submit a report to Congress recommending legislative changes to assist in setting priorities to more effectively and efficiently reduce risks to human health, safety, or the environment.

"SUBCHAPTER III—EXECUTIVE OVERSIGHT

"§ 631. Definitions

"For purposes of this subchapter—

"(1) the definitions under sections 551 and 621 shall apply; and

"(2) the term 'regulatory action' means any one of the following:

"(A) Advance notice of proposed rule making.

"(B) Notice of proposed rule making.

"(C) Final rule making, including interim final rule making.

"§ 632. Presidential regulatory review

"(a) This subchapter shall apply to all proposed and final major rules and to any other rules designated by the President for review.

"(b) The President shall establish a process for the review and coordination of Federal agency regulatory actions. Such process shall be the responsibility of the Director.

"(c) For the purpose of carrying out subsection (c), the Director shall—

"(1) develop and oversee uniform regulatory policies and procedures, including those by which each agency shall comply with the requirements of this chapter;

"(2) develop policies and procedures for the review of regulatory actions by the Director; and

"(3) develop and oversee an annual governmentwide regulatory planning process that shall include review of planned significant regulatory actions and publication of—

"(A) a summary of and schedule for promulgation of planned agency major rules;

"(B) agency specific schedules for review of existing rules, including under section 610;

"(C) a summary of regulatory review actions undertaken in the prior year;

"(D) a list of major rules promulgated in the prior year for which an agency could not make the determinations that the benefits of a rule justify the costs under section 623(d);

"(E) identification of significant agency noncompliance with this chapter in the prior year; and

"(F) recommendations for improving compliance with this chapter and increasing the efficiency and effectiveness of the regulatory process.

"(d)(1) The review established under subsection (b) shall be conducted as expeditiously as practicable and shall be limited to not more than 90 days.

"(2) A review may be extended longer than the 90-day period referred to under paragraph (1) by the Director or at the request of the rule making agency to the Director. Notice of such extension shall be published promptly in the Federal Register.

"§ 633. Public disclosure of information

"(a) The Director, in carrying out section 632, shall establish procedures to provide public and agency access to information concerning review of regulatory actions under this subchapter, including—

"(1) disclosure to the public on an ongoing basis of information regarding the status of regulatory actions undergoing review;

"(2) disclosure to the public, not later than the date of publication of a regulatory action, of—

"(A) all written correspondence relating to the substance of a regulatory action, including drafts of all proposals and associated analyses, between the Administrator or employees of the Administrator and the regulatory agency;

"(B) all written correspondence relating to the substance of a regulatory action between the Administrator or employees of the Administrator and any person not employed by the executive branch of the Federal Government; and

"(C) a list identifying the dates, names of individuals involved, and subject matter discussed in significant meetings and telephone conversations relating to the substance of a regulatory action between the Administrator or employees of the Administrator and any person not employed by the executive branch of the Federal Government; and

"(3) disclosure to the regulatory agency, on a timely basis, of—

"(A) all written correspondence relating to the substance of a regulatory action between the Administrator or employees of the Administrator and any person not employed by the executive branch of the Federal Government; and

"(B) a list identifying the dates, names of individuals involved, and subject matter discussed in significant meetings and telephone conversations relating to the substance of a regulatory action between the Administrator or employees of the Administrator and any person not employed by the executive branch of the Federal Government.

"(b) Before the publication of any proposed or final rule, the agency shall include in the rule making record—

"(1) a document identifying in a complete, clear, and simple manner, the substantive changes between the draft submitted to the Administrator for review and the rule subsequently published;

"(2) a document identifying and describing those substantive changes in the rule that were made as a result of the regulatory review and a statement if the Administrator suggested or recommended no changes; and

"(3) all written correspondence relating to the substance of a regulatory action between the Administrator and the agency during the review of the rule, including drafts of all proposals and associated analyses.

"(c) In any meeting relating to the substance of a regulatory action under review between the Administrator or employees of the Administrator and any person not employed by the executive branch of the Federal Government, a representative of the agency submitting the regulatory action shall be invited.

"§ 634. Judicial review

"The exercise of the authority granted under this subchapter by the President, the Director, or the Administrator shall not be subject to judicial review in any manner.".

(b) PRESIDENTIAL AUTHORITY.—Nothing in this Act shall limit the exercise by the President of the authority and responsibility that the President otherwise possesses under the Constitution and other laws of the United States with respect to regulatory policies, procedures, and programs of departments, agencies, and offices.

(c) TECHNICAL AND CONFORMING AMENDMENTS.—

(1) TABLE OF SECTIONS.—Part I of title 5, United States Code, is amended by striking the chapter heading and table of sections for chapter 6 and inserting the following:

"CHAPTER 6—THE ANALYSIS OF REGULATORY FUNCTIONS

"SUBCHAPTER I—ANALYSIS OF REGULATORY FLEXIBILITY

"SUBCHAPTER II—REGULATORY ANALYSIS

"SUBCHAPTER III—EXECUTIVE OVERSIGHT

"631. Definitions.
"632. Presidential regulatory review.
"633. Public disclosure of information.
"634. Judicial review.".

(2) SUBCHAPTER HEADING.—Chapter 6 of title 5, United States Code, is amended by inserting immediately before section 601, the following subchapter heading:

"SUBCHAPTER I—ANALYSIS OF REGULATORY FLEXIBILITY".

SEC. 4. COMPLIANCE WITH THE UNFUNDED MANDATES REFORM ACT OF 1995.

Compliance with the requirements of subchapter II of chapter 6 of title 5, United States Code (as added by section 3 of this Act), shall constitute compliance with the requirements pertaining to the costs and benefits of a Federal mandate to the private sector in sections 202, 205(a)(2), and 208 of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1532, 1535(a)(2), and 1538).

SEC. 5. EFFECTIVE DATE.

Except as otherwise provided in this Act, this Act shall take effect 180 days after the date of enactment of this Act, but shall not apply to any agency rule for which a notice of proposed rule making is published on or before 60 days before the date of enactment of this Act.

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